COMPOSED BY:

CSC DSMH Vereniging van Deskundigen Steriele Medische Hulpmiddelen NVKF VHIG SEVA wibaz

Professional Standard Handbook

FLEXIBLE ENDOSCOPES

Cleaning and Disinfection

2011

PROFESSIONAL STANDARD HANDBOOK

FLEXIBELE ENDOSCOPES

Cleaning and Disinfection

Published in commission of
CSC
SEVA
VDSMH
VHIG
NVKF
VZI
WIBAZ

by: the Advisory Board Cleaning and Disinfection Flexible Endoscopes (SFERD)

version 2.1, 2011

This document has a legitimacy of 3 years. The SFERD invites you to send your reactions to this document by means of the response form (appendix 19). Please send this to the secretary of SFERD: J.C. van Bergen Henegouw, j.vbergenhenegouw@hagaziekenhuis.nl

This document may be reproduced and distributed freely provided the SFERD is listed as the author.

In April 2011, the Professional Standard Handbook 2010 version 2.0 was awarded the VHIG Infection Prevention Price; the accompanying sum of money was spent on the translation of the handbook in English. This resulted in the Professional Standard Handbook 2.1 English version.

PREFACE

version 2.1, September 2011

In 1993, the Health Care Inspectorate (IGZ) pointed to the risks of using inadequately cleaned and disinfected flexible endoscopes [ref 1-2].
Gradually the development from manual to machine disinfection was put into practice. From the occupational health and safety regulations (ARBO) a ban on working with open containers glutaraldehyde was enforced, which accelerated the conversion to machine disinfection. The IGZ-reports from 2000 and 2004 [ref 3-4] show an insufficient compliance of the existing guidelines in the field of cleaning and disinfection, such as the guideline of the Dutch Workingparty on Infection Prevention (WIP) [ref 5]. Based on frequent reports of incidents in this field, the IGZ was obliged to further tighten the supervision by keeping on showing the hospitals their responsibilities regarding patient safety.

One of the recommendations by the IGZ was the appointment of a flexible endoscopes decontamination expert (DSRD). These experts sought each other through various communication channels to discuss problems. This led to frequent meetings of these professionals nationwide. These meetings resulted in a profitable collaboration of four professional associations with involvement of this field:

- The Sterilization Association of the Netherlands (CSC)
- The Dutch Nurse Association; division Gastroenterology and Hepatology (V&VN, SEVA)
- The Dutch Society of Experts on Sterile Medical Devices (VDSMH)
- The Dutch Society of Infection Prevention and Control in the Health Care Setting (VHIG)

From this collaboration the Advisory Board Cleaning and Disinfection Flexible Endoscopes (SFERD) was established mid-2006. In accordance with the formulated project plan, this advisory board has started with the development of this Professional Standard Handbook Cleaning and Disinfection Flexible Endoscopes, in which existing regulation in the field of cleaning and disinfection of flexible endoscopes is translated into a practical standard.

The choice of the SFERD to publish a first version this Professional Standard Handbook as a dynamic document in 2009, turned out link up with the developments in the field, which are dynamic as well. Due to the publication of the first version, contacts were tightened and strengthened. This has led to a positive contribution of different scientific professional associations, the IGZ, the WIP, the NEN workgroup Cleaning and Disinfection, and mainly the technical professional associations in healthcare:

- Dutch Society for Medical Physics (NVKF)
- Dutch Society of Clinical Engineers (VZI)
- Taskgroup Instrumentation Management University Hospitals (WIBAZ)

They united in the Federation for Medical Technology and contributed as such as member of the SFERD to this second version of the Professional Standard Handbook. This collaboration has, in our opinion, led to the clarification of the structure of the Professional Standard Handbook. Furthermore, this collaboration has yielded a profitable discussion in the field of validation, which has resulted in a more distinct validation policy.
Next to the representatives of the involved associations, a major contribution was given by the workgroup Validation.

freely provided the SFERD is listed as the author

This workgroup consisted of the SFERD members, complemented by:
Klaartje Weijdema, infection prevention adviser/DSRD Diakonessenhuis, Utrecht
Gerband Boelens, DSMH/DSRD Meander MC, Amersfoort
Adrie de Bruijn, researcher RIVM, Bilthoven

In April 2011, the Professional Standard Handbook was awarded the VHIG Infection Prevention Price; the accompanying sum of money was spent on the translation of the handbook in English. For this reason, the document has been critically edited once again by the members of the SFERD. Furthermore, with this the discrepancies with the WIP, in agreement with IGZ, WIP, and ENT-association are removed.[1]

The SFERD hopes that this handbook proves to be a valuable document for your daily practice and invites you to remain critical and keep submitting comments, recommendations, and new developments. The SFERD pursues that this version is valid for a period of three years.

On behalf of all SFERD members,

Federation for Medical Technology, KMT
Job Gutteling, medical physicist/head of Medical Technology, OLVG, Amsterdam

The Dutch Nurse Association; division Gastroenterology and Hepatology,V&VN-SEVA
Nel Blom, endoscopy-nurse, St. Lucas Andreas Hospital, Amsterdam

Sterilization Association of the Netherlands, CSC / SVN
Peter van Alphen, head CSA FlevoHospital, Almere

Dutch Society of Experts on Sterile Medical Devices, VDSMH
Carol te Beest, DSMH/DSRD Maasstad Hospital, Rotterdam
John van Bergen Henegouw (secretary), DSMH/DSRD HagaHospital, Den Haag

Dutch Society for Infection Prevention and Control in the Health Care setting, VHIG
Paul Steegh, adviser infection prevention Jeroen Bosch Hospital, 's-Hertogenbosch
Kees Ballemans (president), DSRD University Medical Center, Utrecht

TABLE OF CONTENTS

TABLE OF CONTENTS 4
LIST OF DEFINITIONS 6
COMPOSITION OF THIS DOCUMENT 8

1. LEADERSHIP: VISION AND ORGANISATION 9
1.1 Introduction 9
1.2 Starting points 9
1.3 Organisation and Vision of the SFERD 10

2. STRATEGY & POLICY 12
2.1 Organisation, cleaning & disinfection 12
2.2 Centrally located versus local disinfections units 13
2.3 Quality system 14

3. HUMAN RESOURCE MANAGEMENT 15
3.1 Responsibility and competence 15
3.2 Training and education 17

4. RESOURCE MANAGEMENT 19
4.1 Building and interior 19
4.2 Acquisition of endoscopes, washer-disinfectors and accessories 22
4.3 Schedule of requirements endoscopes, washer-disinfectors and drying cabinet 22

5. PROCESS MANAGEMENT 24
5.1 Primary process: cleaning, disinfecting and drying flexible endoscopes 24
5.2 Cleaning, disinfection, and/or sterilisation of accessories 34
5.3 Disinfection of TEE transducers 36
5.4 Installation of a washer-disinfector 37
5.5 Risk inventory and evaluation 38
5.6 Traceability of endoscopes and patients 40

6. APPRECIATION BY CUSTOMERS 42
6.1 Patient safety 42
6.2 Turn-over / availability endoscopes 42

7. APPRECIATION BY HEALTH CARE STAFF 43

8. APPRECIATION BY SOCIETY 44
8.1 Incident management 44
8.2 Aspects on the application of incident management 45
8.3 Phases in the incident procedure 46
8.4 Amplification on phases in the incident procedure 47
8.5 Image damage on the institution 49

9. RESULTS 50

10. IMPROVEMENT AND INNOVATION BY AUDIT & CONTROL 51
10.1 Performing audits 51
10.2 Risk inventory and evaluation 51
10.3 Agreements on management 51
10.4 Assessment of management 52
10.5 Conventions about validation 52
10.6 Validation of the washer-disinfector 56
10.7 Periodical inspections, verification specifications, and other controls 58

freely provided the SFERD is listed as the author

10.8 Other controls washer-disinfector 61
10.9 Release washer-disinfector for use 61
10.10 Validation drying/storage cabinets 62
10.11 Control Flexible Endoscopes 63

Appendix 1- Bibliography 66
Appendix 2 – Form for conveyance of a damaged or leaking endoscope 68
Appendix 3 – Decontamination form 69
Appendix 4 – Routine application of daily maintenance of the washer-disinfector 70
Appendix 5 – Release form for flexible endoscopy after maintenance 71
Appendix 6 – System specifications of the washer-disinfector 72
Appendix 7 – Determination of microbiological quality 76
Appendix 8 – Flow chart for microbiology tests on flexible endoscopes 79
Appendix 9 - Flow chart for microbiology tests on the post-disinfection rinse water 80
Appendix 10 - Estimation sheet on microbiology in endoscopes and/or washer disinfectors 81
Appendix 11 - Ninhydrine swab test 82
Appendix 11 - Ninhydrine swab test 82
Appendix 12 - Hemoglobin swab test 83
Appendix 13 – Release form flexible endoscopes 85
Appendix 14 – Schedule of requirements for washer-disinfector 86
Appendix 15 – Requirements for flexible endoscopes 88
Appendix 16 – Schedule of requirements for drying cabinet 89
Appendix 17 – Audit form endoscopy 91
Appendix 18 – Audit form endoscopy – Medical Technology 100
Appendix 19 – Response form for contributions for improvement of the handbook 104

LIST OF DEFINITIONS

Adverse event
An adverse event is an unforeseen event, in other words a deviation from the protocols and work instructions.

Contact person
Person at the department where the washer-disinfector is in use, who has the authority to execute repairs, maintenance, tests, and checks, as well as the responsibility for daily and weekly inspection; e.g. head of the department.

Drying Cabinet, a.k.a. Endoscope Drying (and Storage) Cabinet
A drying cabinet is a cabinet in which a wet disinfected flexible endoscope can be placed and in which the channels of the endoscope can be connected in order pass compressed filtered air through them. A drying cabinet dries the entire endoscope; the channels and the exterior.

Flexible endoscope
Medical device for looking into body cavities for diagnostic and/or therapeutic purposes.

Incident
An incident is every adverse event that leads to (possible) damage to a patient and/or employee.

Logbook
Digital (or written) document in which all relevant data about inspections, maintenance, malfunctions, and usage is recorded and kept up-to-date.

Maintenance
All the activities, specified by the manufacturer in the maintenance schedule, and preventive replacements of parts to ensure the continuous safe operation of the washer-disinfector.

Manufacturer
The natural or legal person:
1. with responsibility for the design, manufacture, package, and labelling of a device before it is placed on the market under its own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party; or
2. who assembles, packages, precesses, fully refurbishes and/or labels one or more ready-made products and/or assigns to them their intended purpose as a device with a view to their being placed on the market under his own name.

Owner
Board of Directors, Management of the health care facility, its representative(s), and successor(s) who own the washer-disinfector.

Repair
All executed activities to resolve a malfunction in the washer-disinfector.

freely provided the SFERD is listed as the author

Release, functional
A device is functionally released for use if the responsible person, in this handbook the DSRD, regards the device functionally able to function in a safe and effective manner on top of the technical release.

Release, technical
A device is technically released if the responsible department, in this handbook called Medical Technology/ Clinical Physics, has technically released the device for use. In many cases, an additional functional release also needs to be obtained.

Storage Cabinet, a.k.a. Endoscope Storage Cabinet
A storage cabinet is a sealed cabinet with or without overpressure at room temperature, in which a dried flexible scope is stored. The difference between a drying cabinet and a storage cabinet is that in a storage cabinet the channels of the endoscope cannot be connected.

Supplier
Every natural or legal person, who is entitled by the manufacturer to deliver, install, and maintain washer-disinfectors.

User
Trained employee who is authorised to operate a washer-disinfector.

Validation
Validation is the evaluation of the results of measurements, tests, and checks that have been performed in a period, in order to obtain assurance that the washer-disinfector still meets the specifications that the manufacturer has established. Based on the specifications, the manufacturer has declared that the washer-disinfector meets the essential requirements of the Medical Device Directive 93/42/EC. The specifications are the basis for all subsequent measurements, tests, and checks. The results of the measurements and the performed procedures are tested/ evaluated according to the standards and regulations as outlined in this handbook and are recorded in a report together with the underlying information (test reports, data from measurements, statements, etc).

Washer-disinfector
Machine designed to deliver an automatic process for cleaning and disinfection of flexible endoscopes.

Abbreviations

ARBO	Working conditions
CSA	Central Sterilization Department
DSMH	Expert on Sterile Hospital Supplies
DSRD	Expert on Endoscope Cleaning and Disinfection
EFQM	European Foundation for Quality Management
IGZ	Dutch Health Care Inspectorate
MT	Medical Technology Department
NIAZ	Netherlands Institute for Accreditation in Healthcare
PDCA	Plan-Do-Check-Act
SFERD	Advisory Board Cleaning and Disinfection Flexible Endoscopes
TEE	Transesophageal Echocardiography
VMS	safety management system
VWS	Ministery of Health, Welfare and Sport
WIP	Dutch Workingparty on Infection Prevention

COMPOSITION OF THIS DOCUMENT

The EFQM-model[1] is a valuable resource for healthcare institutions and professionals and gains increased popularity in healthcare. The model provides a structure to combine the interests of patients with the organisational goals in a balanced manner. Moreover, the model turns out to function as means of communication between Board of Directors, healthcare professionals, managers, department heads, and employees, due to the unambiguous method and classifications into 9 fields and the improvement cycle; as illustrated in the figure below:

The model contains five coherent *fields of organisation*:

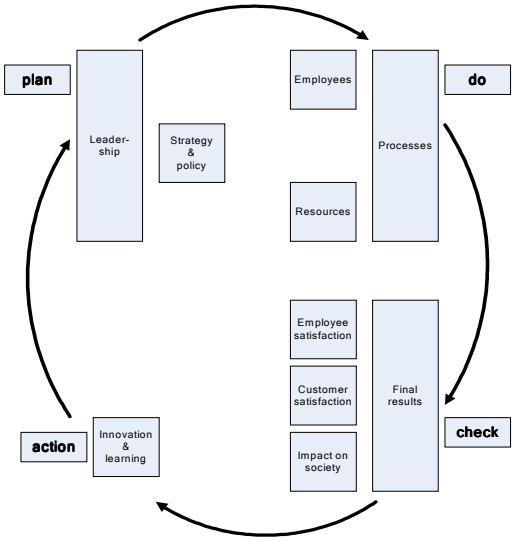


***Figure 1** –The EFQM model with the Plan-Do-Check-Act cycle, as applied in this SFERD handbook*

PLAN:
Leadership
Strategy & Policy
DO:
Employees
Resources
Processes

In addition to this, four fields of results are defined:
CHECK:
Customer satisfaction
Employee satisfaction
Impact on society
Final results

Testing and improving of processes is shown in the last field:
ACT:
Innovation & learning

The SFERD has made good use of this model while striving for the development of a guaranteed quality system. The PDCA cycle of the EFQM model is addressed in the following chapters:

PLAN:	chapter 1	Leadership: Vision and Organisation
	chapter 2	Strategy & Policy
DO:	chapter 3	Human Resource Management
	chapter 4	Resource Management
	chapter 5	Process Management
CHECK:	chapter 6	Appreciation by Customers
	chapter 7	Appreciation by Healthcare staff
	chapter 8	Appreciation by Society
	chapter 9	Results
ACT:	chapter 10	Improvement and Innovation by Audit & Control

[1] The EFQM is an independent foundation, established in 1991 at the initiative of the Ministry of Economic Affairs under the name Dutch Quality Institute.

freely provided the SFERD is listed as the author

1. LEADERSHIP: VISION AND ORGANISATION

1.1 Introduction

Flexible endoscopes are used for diagnostic and therapeutic applications. Because the same endoscopes are used in different patients, it is of importance that cleaning, disinfection and/or sterilisation occur in an adequate manner. Inadequate cleaning and disinfection has negative consequences, such as:

Transfer of micro organisms between patients

Endoscopy related transfer of gram-negative bacteria, mycobacteria, as well as fungi have frequently been described in literature. Transfer of hepatitis B, C, and HIV cannot be excluded [ref 31-35].

Wrong diagnosis

Next to the risk of infection for patients, there is the danger of wrong diagnosis resulting in the unnecessary use of (antibiotic) therapy. In case of inadequately cleaned and disinfected endoscopes, tissue of patients can stay behind. This material can lead to a wrong diagnosis during diagnostic examination of the subsequent patient. Besides a wrong diagnosis regarding for example mycobacteria, this could concern malignant cells [ref 7-9, 36-38].

In several Dutch hospitals, incidents with flexible endoscopes have occurred during the past years. As a result, hundreds of patients were recalled to test for HBV, HCV, and HIV.

The Health Care Inspectorate (IGZ) has pointed to the responsibilities of the hospitals repeatedly.

The goal of the Advisory Board Cleaning and Disinfection Flexible Endoscopes (SFERD) is the development of this Professional Standard Handbook Flexible Endoscopes, in which the existing regulation in the field of cleaning and disinfection of flexible endoscopes is translated into a practical field standard. This includes, among others, a validation and release procedure, a complaints and recall procedure and an audit and control system.

1.2 Starting points

Primum non nocere (above all no damage), with this lofty phrase the medical world points out that we do not want to cause any harm to our patients. This means that we need to prevent that exogenous transfer of microorganisms could occur during examination or treatment with the use of a flexible endoscope.

In the IGZ reports '*Cleaning and disinfection of scopes too flexible?*' dated April 2002 and *'Follow-up study endoscope disinfection'* dated June 2004, the IGZ already pointed out the omissions in cleaning and disinfection of flexible endoscopes. The IGZ emphasises the compliance to the professional standard *'Cleaning and disinfection of endoscopes'* of the WIP, whose first version dates from 1992 and the prevailing

version of 2009 [ref 5]. In 2007, the safety program "*Avoid harm, work safely"* [ref 16] was presented to the Minister of Health, Welfare and Sport (VWS) Ab Klink by Inspector General for Healthcare Gerrit van der Wal. This safety program proposes the introduction of a safety management system (VMS) from January 1, 2008 and starts with the reduction of hospital infections. The core of a VMS consists of a risk inventory, systematics for (safely) reporting incidents, a method for incident analysis, and systematics to manage the resulting recommendations and improvement measures. Introduction of these systematics within the field of cleaning and disinfection of flexible endoscopes will have a positive effect on patient safety.

At European level, attention is paid to ensuring the quality of washer-disinfectors through standard EN-ISO 15883 [ref 10]. To ensure the technical specifications, validation tests are specified in this standard. Part 1, 4 and 5 of EN-ISO 15883 give overviews of the test program for endoscope washer-disinfectors.

1.3 Organisation and Vision of the SFERD

The development of an adequate VMS for the cleaning and disinfection of flexible endoscopes causes many points of discussion in practise. This has lead to increasingly frequent encounters of infection prevention advisers within the VHIG on the digital discussion forum. It soon became apparent that endoscopes disinfection and patient safety extend beyond the field of attention of VHIG and the discussion was expanded to the CSC, VDSMH and SEVA. This exchange of thoughts, supported by the boards of these associations, has led to the establishment of the Advisory Board Cleaning and Disinfection Flexible Endoscopes (SFERD). After the publication of the first edition of this manual in 2009, the SFERD is extended with the NVKF, VZI, and WIBAZ in order to focus on the technological aspects as well.

The advisory board worked on sub problems within working groups. For this second version, in particular the working group Validation has worked on a new approach to validation and the addition of drying cabinets to the validation process.

The SFERD strives for a future durability of 3 years with this version of the SFERD Professional Standard Handbook. In the future, the SFERD will take care that relevant developments in the field of cleaning and disinfection of flexible endoscopes will be incorporated into new version of this handbook.

The SFERD has focussed on abovementioned enforced professional and international standards. It was the starting point to prevent conflict of the content of this handbook and existing standards. Nevertheless, there are issues were the vision of the SFERD does not entirely match the mentioned standards.
In the view of the SFERD, automated cleaning and disinfection should be the primary choice for all flexible endoscopes, if not the only choice. Automated disinfection is the only reproducible method of disinfection that ensures tracking and tracing. Manual disinfection should only be seen as an emergency procedure for endoscopes without channels.

Despite the fact that this handbook focuses on flexible endoscope, the SFERD wants to emphasise that the washer-disinfector should not be used for other medical devices that lack a compatibility statement, as provided by the supplier of the washer-disinfector. This means that rigid endoscopes that are used in naturally-non-sterile body cavities can be disinfected in the washer-disinfector only if this is indicated by the supplier of the washer-disinfector. When single-use devices become available for endoscopes or probes, these devices will be preferred.

freely provided the SFERD is listed as the author

In addition, the SFERD fully supports the principle of the IGZ to have cleaning and disinfection of endoscopes performed by qualified personnel. The feasibility of this goal will be enhanced if the cleaning and disinfection is centralised as much as possible, so that the activities will be executed by a specialized group of employees. In order to sufficiently train this group, the SFERD appeals to participating member organisations to develop a thorough educational program.

Despite the fact that evidence-based guidelines were pursued, the SFERD must conclude that its advices in this handbook are based mainly on best practice and common sense. Apparently ample challenges exist for research and publications about aspects of the cleaning and disinfection procedures of flexible endoscopes.

2. STRATEGY & POLICY

2.1 Organisation, cleaning & disinfection

Safety management is only successful if responsibilities are clearly designated. Both the VMS report and the abovementioned IGZ reports demand the assignment of responsibilities. Commitment of Executive Board or Boards of Directors is explicitly mentioned. Furthermore, the involvement of all healthcare providers and medical specialists is essential for successful implementation of the VMS. The IGZ recommends the appointment of an Expert on Scope Cleaning and Disinfection (DSRD), to ensure a successful endoscopes management plan. In practice, this responsibility is assigned to the infection prevention advisers, Experts Sterile Hospital Supplies (DSMH), or heads of the Central Sterilization Department or the Endoscopy Department.

The Executive Board or Board of Directors is at all times responsible for quality and continuity of the provided care, in accordance with the Dutch Care Institutions Quality Act. The operational responsibility is delegated at a managerial level to the appointed organisational managers or management teams. These can be management teams of scope-disinfecting and/or scope-utilizing departments (decentralised). If endoscopes are disinfected centrally the management can be part of the Central Sterilization Department (CSA) or Facility Services (support services). Intermediate forms with pre-cleaning at an (outpatient) department, followed by adequate logistics and central automated disinfection, aided by the input from experts (CSA) employees, provide a safe construction for cleaning and disinfection of endoscopes. As a result of outsourcing, the care for endoscopes disinfection can be designed even completely outside the organisation. In all organisational models, protocols, logging, tracking and tracing should adequately be installed and periodically audited.

Organisational managers as well as professionals of scope-disinfecting and/or scope-utilizing departments have the task to guarantee in the interest of the patient the quality of care at the operational level respectively the application level when using medical devices and to prevent inexpert use.

The Medical Technology / Clinical Physics steers the life cycle of medical equipment. In addition, the department supports and provides recommendations on the quality and safety of medical devices from a technical point of view.

The department Hygiene and Infection Prevention contributes with expertise in the areas of cleaning / disinfecting, advising solicited or unsolicited on qualitatively legitimate patient care.

The DSRD monitors operational conditions and procedures for the use of endoscopes, based on laws and guidelines. Furthermore, the DSRD detects improvement measures in patient care on behalf of the Executive Board or Board of Directors of the institution or his delegate.

As part of the purchasing procedure the DSRD verifies the required compatibility declarations of endoscopes, cleaning and disinfection equipment and process chemicals, in the context of EN-ISO 15883 for the organization with the suppliers.

freely provided the SFERD is listed as the author

2.2 Centrally located versus local disinfections units

For a proper cleaning and disinfection of flexible endoscopes, one should provide appropriate facilities and equipment and one should ensure that the staff is competent in the field of cleaning and disinfection of endoscopes. The extend and design of the cleaning and disinfecting area should include (physical) separation between the clean and contaminated area. Considering the above, a central cleaning and disinfection area is preferred over a local facilities.

SCENARIO 1 – Central endoscopy units and cleaning/disinfection
Endoscopy units of various specialties adjacent to (or near) the cleaning and disinfection unit.

Advantages	Disadvantages
Spatial facilities and the expertise are better used as the activities carried out by a smaller group	Difficult to realize in existing buildings
Personnel and equipment are available more efficiently. Stock material can be reduced	Depending on the location in the hospital more costs for transportation and logistics problems
More uniformity	
The quality assurance is more manageable so less risks for the patient	

N.B.: There must be consultation between the various user specialties about the facilities.

SCENARIO 2 – Central cleaning/disinfection
Endoscopic treatment units at a distance from the cleansing and disinfection room.

Advantages	Disadvantages
Spatial facilities and the expertise are better used as the activities carried out by a smaller group	Additional logistics call for means of transportation and personnel
Personnel and equipment are more efficiently utilised. Stock material can be reduced	Possible need for more flexible endoscopes
More uniformity	
The quality assurance is more manageable so less risks for the patient	

SCENARIO 3 – Decentralised
Per one or more endoscopic treatment units a cleaning and disinfection room.

Advantages	Disadvantages
	Limited expertise of employees
Very concise logistics, high turn over and little transportation	Inefficient use of washer-disinfector and employees
Efficient use of endoscopes	Insufficient coordination between the different departments
	The quality assurance and documentation management is more difficult

Recommendation
For reasons of patient safety, quality assurance, the more efficient use of space, facilities and the expertise of the employees responsible for cleaning and disinfection, central cleaning and disinfection is preferred. This results in better allocation of responsibilities, clear logistics and processes that can be planned.

In the report dating from 2004, the IGZ indicated that the visited hospitals, where disinfection occurs centrally, see apparent advantages of centralisation, such as:

- better spatial facilities;
- activities executed by a smaller group, so that the expertise is better utilized.

2.3 Quality system

The cleaning and disinfection process of flexible endoscopes should to be incorporated in the hospital/departmental quality assurance system. Assurance of the quality of this process should be based on quality thinking and quality cycles (Plan-Do-Check-Act cycles). The conducting of audits, both during purchase and installation of equipment and the implementation of the cleaning and disinfection process should be tested by frequent validations and audits. Documents should be provided with usual management aspects such as production date, validity, author, authorisation, etc. It is essential that there is a right assignment of tasks between the parties involved. Documents for procedures with similar equipment used in different departments are required to show identical instructions (standardisation).

freely provided the SFERD is listed as the author

3. HUMAN RESOURCE MANAGEMENT

3.1 Responsibility and competence

In an organisation where employees work with flexible endoscopes, responsibilities and competences, regarding cleaning and disinfection should be established. Each institution will realise the execution according to the management model. Responsible for the policy on flexible endoscopes, is the Executive Board or Board of Directors; they should, according to IGZ advice, ensure a clear allocation of responsibility concerning the process of cleaning and disinfection. The IGZ is of opinion that a flexible endoscopes decontamination expert should be appointed. For the proper performance of tasks, this officer needs to have appropriate authorities, such as to stop processes. Below is described how the responsibilities can be further realized.

Expert on Endoscope Cleaning and Disinfection (DSRD)

- is responsible for the quality of the processes related to cleaning, disinfecting and storage of flexible endoscopes;
- is responsible for monitoring, assuring and evaluating the process quality through internal audits;
- is responsible for the quality of the provided improvement recommendations resulting from audits;
- ensures that a policy change is translated into the procedures and work instructions;
- is responsible for reporting and convening a policy team, in case of possible emergency regarding endoscopes, where patient safety is at stake;
- advises on the purchase of flexible endoscopes and equipment;
- determines the validation plan in consultation with the Medical Technology / Clinical Physics, the department Infection Prevention and the supplier;
- is responsible for the functional release of the washer-disinfector, the drying cabinet and flexible endoscope after purchase, installation and maintenance.

Manager Endoscopy department

- is responsible for the daily affairs at the endoscopy room (s);
- is responsible for the introduction and testing of new equipment;
- is responsible for providing (re)training and updating knowledge of employees;
- is responsible for reporting and documenting deviations;
- is the manager of the quality documents;
- is responsible for monitoring and recording of the cleaning and disinfection process;
- is responsible for training and supervising new employees.

Manager cleaning and disinfection unit

- is responsible for the entire process, procedures, work instructions and protocols in accordance with laws and regulations concerning cleaning and disinfection of flexible endoscopes;
- is responsible for the updating of procedures, work instructions and protocols;
- is responsible for circumstances in which working conditions are created

- is responsible for the establishment and adherence to enforced agreements;
- is responsible for the purchase and introduction of new cleaning and disinfection equipment for flexible endoscopes;
- is responsible for providing training on behalf of the expertise of the employee.

Medical Practitioner

- is responsible that he / she is adequately informed about prevailing procedures regarding an endoscopy and acts in accordance;
- should report suspected abnormalities and / or failure of prevailing procedures to the manager of the department;
- is responsible to use only well functioning and decontaminated equipment. If in doubt about the status (both cleaning and technical maintenance) the equipment shall not be used;
- is responsible for reporting any malfunction of the equipment and/or flexible endoscope to the manager of the department.

Medical microbiologist

- is responsible for proper processing of microbiological cultures of rinse water, and the endoscope;
- is responsible for interpreting results of microbiological tests;
- is responsible for risk assessment of blood-borne diseases caused by incidents.

Disinfection- and/or Endoscopy-assistant[2]

- is responsible for performing the applicable cleaning and disinfection procedures of flexible endoscopes, the use of washer-disinfectors, drying cabinet and peripheral equipment;
- is responsible for completing the logbook and checklists regarding the use of flexible endoscopes and peripheral equipment;
- is aware of the procedure in case of deviations and / or failure of prevailing procedures;
- is responsible for the registration of patients, endoscope and washer-disinfector information (patient tracking system);
- is responsible for updating his/her own knowledge and training.

Manager department Medical Technology / Clinical Physics

- is responsible for ensuring the quality and safety of medical equipment;
- is responsible for the execution of the prevailing procedures for maintenance and repair of flexible endoscopes and related equipment including execution of validation plan;
- is responsible for recording malfunctions / repairs / maintenance of flexible endoscopes, lend materials and related equipment;
- advises on the purchase of new equipment concerning cleaning and disinfection of flexible endoscopes;
- is responsible for the applicable procedures for the protection of employees;
- reports accidents / abnormalities to the DSRD;

[2] Endoscopy assistant, meaning all assistants at endocopy departments, both GE, Urology, Lungs, and ENT. Regarding the expertise it is recommended that a specifically qualified employee for disinfection is appointed.

freely provided the SFERD is listed as the author

- is responsible for releasing the washer-disinfector or drying cabinet after maintenance (technical release). Thereafter, the DSRD needs to carry out a functional release / validation;
- is responsible for installation, transfer and acceptance of the equipment.

Adviser Infection Prevention

- advises on purchase of washer-disinfectors;
- participates in hygiene audits;
- supports and advises on the development of procedures regarding hygienic aspects;
- advises in case of an incident;
- advises on the purchase of detergents and disinfectants for cleaning and disinfection process for flexible endoscopes.

Purchaser

- coordinates the commercial activities related to the purchase of flexible endoscopes, washer-disinfectors, drying cabinets and peripheral equipment of flexible endoscopes.

3.2 Training and education

Because endoscopes are used for different patients, it is of importance to clean and disinfect in a responsible fashion. The quality of this cleaning and disinfection is largely determined by humans. Therefore, the personnel should be able to adequately perform all duties. The aim of the training of these employees is to educate them sufficiently regarding the knowledge required for adequate performance of their duties. The manager should have insight into which employees are sufficiently trained. In the absence of relevant training offered by third parties, the organisation itself should provide the education of employees.

Starting point
The required training (s) of the employees involved in carrying out cleaning and disinfection should be at least at the level of independent employee, independent professional, or vocational training.

Recurrent training
For breaking in and maintaining the employees' knowledge and skills on cleaning and disinfection, the following education is minimally required:

Introduction program new employee
Each new employee follows an introduction program which includes, among others, the reading of all procedures, cleaning and disinfecting endoscopes, handling equipment, reporting defects and safely working with chemical agents. During this period, the employee is coupled to a supervisor. The supervisor will monitor progress by means of partial qualification lists. After all aspects of introduction have been approved by the management of the department, the employee is allowed to perform activities independently.

Maintaining employee skills
Each employee should maintain their skills / expertise in the field of cleaning and disinfection. This is accomplished by frequent execution of processes and attending of internal and / or external courses, in case of developments in areas such as:

- relevant legislation;
- cleaning methods and machines;
- cleaning and disinfecting agents;
- occupational health and safety / environmental laws;

A copy of the certificate of participation is added to the portfolio of the employee.

Abbreviated competency description

- vocational training certificate and/or or the level of an independent employee, independent professional.
- masters the Dutch language, spoken and written, can read and interpret instructions;
- knowledge regarding contents of protocols and regulations
- applied knowledge of / insight into the activities and practices of other departments and knowledge of functioning of the flexible endoscopes that are used there;
- affinity with hygiene, technology and working with protocols;
- applied knowledge of computerization and automation.

freely provided the SFERD is listed as the author

4. RESOURCE MANAGEMENT

4.1 Building and interior

A primary prerequisite of adequate cleaning and disinfection of endoscopes is that the routing of the endoscope used is such that (potential) contamination of the clean and disinfected endoscope with microbiologically contaminated material (used endoscopes and accessories) is prevented. This goal is preferably achieved by a physical separation of activities. In case the circumstances do not allow for this, a rational sequence of activities in the same area should prevent crossing over of clean and contaminated materials. The extend and design of the cleaning / disinfecting area should be adjusted to the preservation of this principle. To achieve this, the following construction and equipment requirements must be met.

Construction aspects	Requirements / Standards
Surface area and spatial arrangement cleaning / disinfection	Sufficient surface area[3] for placing all necessary facilities, namely: - area for receiving "contaminated" endoscopes - workspace manual pre-cleaning - washer-disinfectors - drying cabinets and storage cabinets for endoscopes - distribution area disinfected endoscopes - hand hygiene facilities - area for waste - area for storage of disinfectants - area for storage of transportation containers and transportation trolleys - area for a possible container washer-disinfector - area for manoeuvring an washer-disinfector for repair When using separate areas (clean and contaminated), passing of empty transport containers from contaminated to clean should be taken into account, where plastic sleeves in the container liners are used and / or pass through container washer disinfectors.
Spatial separation	Sufficient surface area for spatial separation of clean and contaminated goods
Future	Take into account the future developments in technique, data processing, necessary equipment and possible extension of services.
Water	Back flow of water from the washer-disinfector to the water distribution system should not be possible. The required water quality depends on the type of disinfector and the cleaning agent and disinfectant. Take the area for any water filters into account.
Electricity	Comply with the NEN 1010, class 0 (technical quality requirements) [ref 14]

[3] The building commission recommends in the building construction standard "Consultation department, outpatient treatment and general organ function studies" a cleaning and disinfection area of 9m^2 per two endoscopy rooms.

Air conditioning	Air conditioning can be arranged according to the "Building standards central sterilization department" [ref 12] In the cleaning area, additional suction sections need to be placed due to aerosols; reinfection of the disinfected endoscopes by aerosols generated during pre cleaning should not be possible.
Extraction	Extraction of the washer-disinfector according to the recommendation of the manufacturer. Point extraction above a work bench in accordance with occupational health and safety policy.
Disposal of disinfectants	According to management plan of hazardous materials / environmental permit. Also see the safety information sheet regarding disinfectant.
Wall and floor coverings	Smooth, impact resistant, easy to clean, resistant to detergents and disinfectants. Wet floors should not become slippery.
Doors and windows	Preferably automatic door, or by means of foot operation open / close. Windows in accordance with occupational health and safety requirements.
Lighting	According to standards, no shading.
Receiving area for contaminated endoscopes	Sufficient space for the receipt and temporary storage of contaminated endoscopes including the means of transport.
Distribution area clean endoscopes	Sufficient space for the storage and distribution of clean endoscopes including transportation (option: pass-through in the wall)
Storage operational stock of chemicals at the department	Fluids in drip tray, detergents and disinfectants according to occupational health and safety / environmental requirements, also see the safety information sheets regarding the agents
Waste	According to hospital environmental plan, enough space for separated waste
Ceiling	Ceiling made of dust free and moisture-resistant material and enough space above ceiling for technology

freely provided the SFERD is listed as the author

Interior design aspects	Requirements / Standards
All equipment	Should be provided with information visible to the user and technician (e.g. a printed sticker) with regard to the period in which the device may be used - considering the maintenance status.
Leak tester	In such a vicinity of the sink that no contact between water and electrical facilities is possible
Endoscope-disinfector	Sufficient space for the required number, setup, loading / unloading and operation. Consider pass-trough equipment. Utilities; compressed air, water, electricity, ventilation, data, sewer connection
Drying- and Storage cabinets	Spatially separated from contaminated work. Consider hatches. Utilities; medical grade air, electricity, data processing.
Sink and work bench	Sink (stainless steel) with rounded edges equipped with water pistol. Sizes according to length endoscope. Work bench 'contaminated', area sufficient for the activities, taking an ultrasonic bath into account. Smooth finish without seams with water barrage. Rear wall of the work bench should be smooth and easy to clean and seamlessly connected to work bench. Cabinet space above work bench to store the materials used in manual pre-cleaning. Work bench 'clean', clearly separated spatially from contaminated work bench, including compressed air pistol. Cabinet space above work bench for storage of the accessoires for clean endoscopes.
Ultrasonic bath [4]	Possibly integrated into the pre-cleaning work bench. Utilities: water, sewer connection, and electricity.
Clean/ contaminated transport	Necessity depending on central/decentralised work system. Clean and contaminated transport spatially separated.
Cleaning and disinfection transport containers and utilities	Necessity depending on central/decentralised work system. Using an automated washer-disinfector, taking into account space and facilities. Utilities for a washer-disinfector: compressed air, water, electricity, ventilation, data- and sewer connections.
Hand hygiene	At "contaminated" side of work bench: sink whwith a foot or elbow operated tap alcohol and soap dispenser with elbow operation towel dispenser At the "clean" side of work bench: Alcohol dispenser with elbow operation.
Occupational health and safety Administrative workspaces	According to the hospitals' occupational health and safety plan, an eye shower is minimally required. If a PC is used, the keyboard should be cleanable. Network connection and proper lighting.
General	Possibility to early warning in case of emergencies.

[4] Materials, which are ultrasoniccaly cleanden, are generally sterilised. Preferably, the ultrasonic cleaning is carried out at the CSA or central disinfection unit or replacement with single-use devices is persued.

4.2 Acquisition of endoscopes, washer-disinfectors and accessories

The purchase / replacement of equipment flowchart (figure 2) illustrates the cycle on the acquisition and/or replacement of endoscopes, water-disinfectors, and/or drying cabinets. The flowchart can be used as a guide to involve relevant disciplines within the hospital in the selection of equipment.

Where a similar type of washer-disinfector is used in multiple departments within the institution, the use of the same detergents and disinfecting agents for the various phases of (manual and/or mechanical) cleaning and disinfection (standardization) is preferred.[5]

4.3 Schedule of requirements endoscopes, washer-disinfectors and drying cabinet

The requirements are an assessment tool in market research for purchase and are designed as a checklist, divided into the following categories of requirements:

- Statutory;
- Validation;
- Health and environment;
- Techn(olog)ical;
- Process;
- Cleaning and disinfection;
- User convenience;
- Traceability and registration;
- Installation condition;
- Maintenance;
- Support / education;

These main categories consist of subcategories. The supplier needs to indicate with yes/no whether the mentioned criterion is present. It is also possible to add comments and refer to enclosed documents. The schedule of requirements contain legal requirements and points for attention set by the SFERD. It is up to the hospital to value the points of attention or to request certain explanation or information.

A predetermined risk analysis, as is among others recommended by the NVKF [ref 29], is necessary to indicate what will be points of attention in the continuation of the acquisition process and what specific contributions by officials are required for this.

The appendices contain examples of requirements. The requirements cannot be copied from one hospital to the next and should modified to fit the situation and needs of the particular hospital. The documents in the appendices can be used as a starting point.

See appendix 14	Schedule of requirements for washer-disinfector
See appendix 15	Schedule of requirements for flexible endoscope
See appendix 16	Schedule of requirements for drying cabinet

[5] If the compatibility of all endoscopes with the same chemistry is allowed

freely provided the SFERD is listed as the author

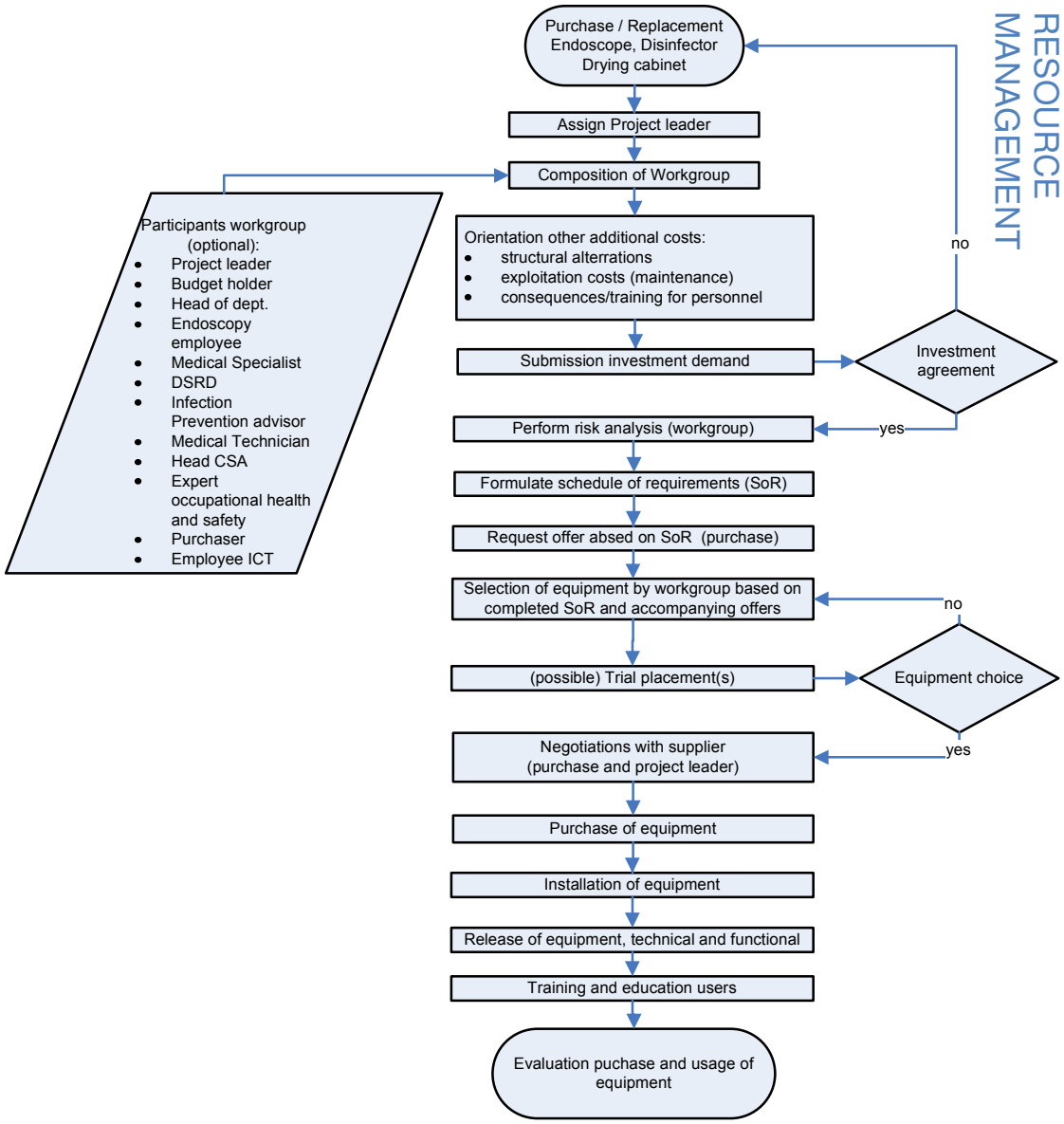


Figure 2 –*Flowchart purchase/replacement endoscope, disinfector and/or endoscope drying cabinet*

5. PROCESS MANAGEMENT

5.1 Primary process: cleaning, disinfecting and drying flexible endoscopes

Processes are the basis of every organisation. A process shows the order and interactions of several activities that should be executed during a process. By providing insight into the risks, these can be minimised and the processes can be organised and improved efficiently.
By applying risk management, optimal patient safety is achieved. This means that the risks arising from human or technical and/or organisational imperfections in the process of health care provision are eliminated as much as possible.

The different steps of the primary process are described in the flowchart (figure 3). The risks are presented in a risk table (section 5.5 and 8.2). This provides overview and clarity for all parties involved. The administrative measures have been described for the most important risks.

This chapter describes the following process steps:

STEP 1	Preparation of the endoscope before use
STEP 2	Transport of disinfected (dry) endoscope
STEP 3	Pre-cleaning in the endoscopy room by the operator
STEP 4	Transport of an used endoscope
STEP 5	Preparations before cleaning and disinfecting of the endoscope
STEP 6	Leak testing of the endoscope
STEP 7	Handling of a damaged endoscope
STEP 8	Manual pre-cleaning of the endoscope
STEP 9	Automated cleaning and disinfection in the washer-disinfector
STEP 10	Release of the flexible endoscope after disinfection
STEP 11	Drying the flexible endoscope
STEP 12	Reprocessing after office hours
STEP 13	Loan flexible endoscopes and accessories
STEP 14	Deviations from the primary process of channel less endoscopes
STEP 15	Replacing the detergent and disinfectant containers
STEP 16	Self-disinfection of the washer-disinfector
STEP 17	Maintenance of the washer-disinfector

freely provided the SFERD is listed as the author

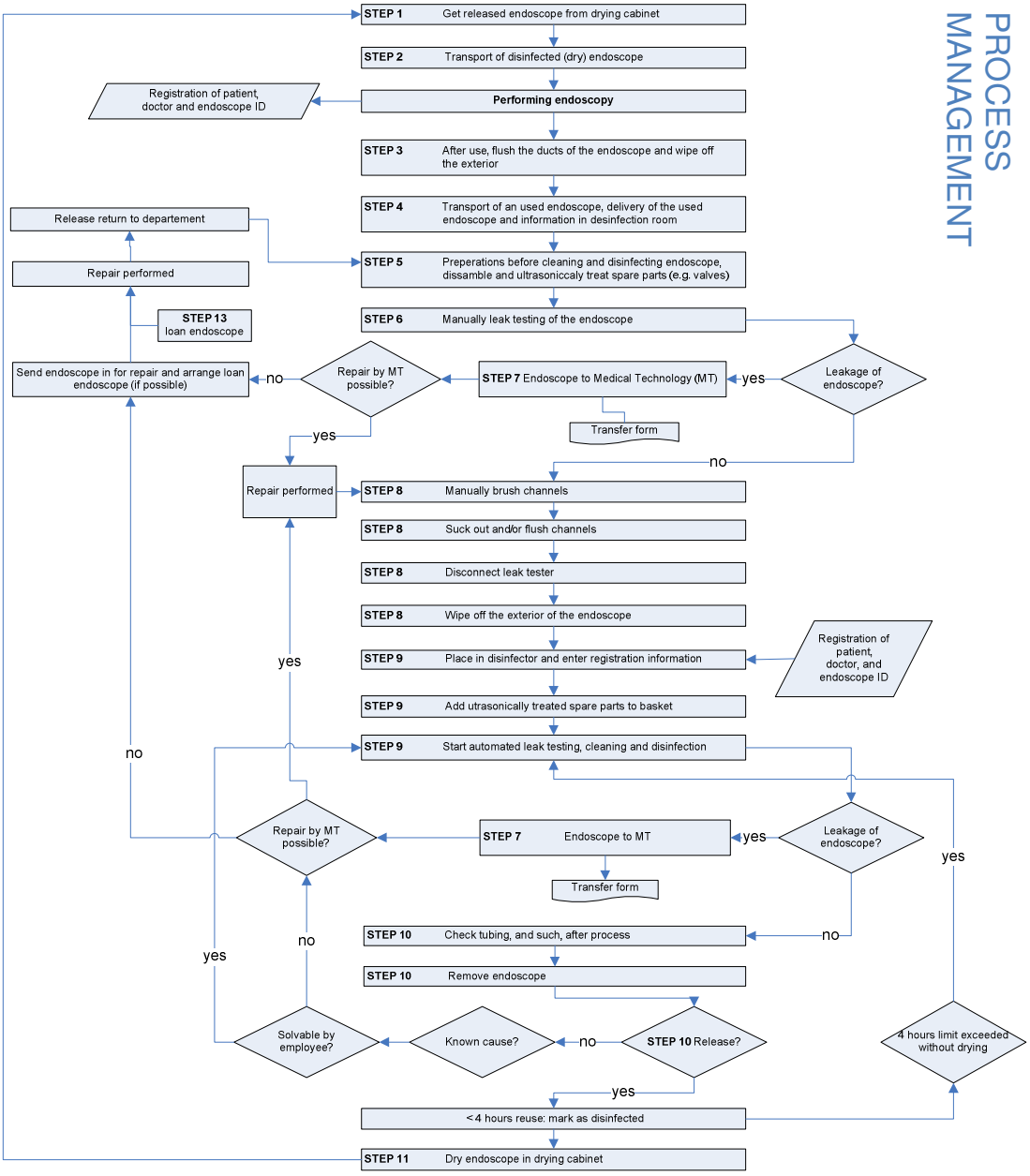

STEP 1 Get released endoscope from drying cabinet
STEP 2 Transport of disinfected (dry) endoscope
Registration of patient, doctor and endoscope ID
Performing endoscopy
STEP 3 After use, flush the ducts of the endoscope and wipe off the exterior
STEP 4 Transport of an used endoscope, delivery of the used endoscope and information in desinfection room
Release return to departement
STEP 5 Preperations before cleaning and disinfecting endoscope, dissamble and ultrasoniccaly treat spare parts (e.g. valves)
Repair performed
STEP 13 loan endoscope
STEP 6 Manually leak testing of the endoscope
Send endoscope in for repair and arrange loan endoscope (if possible)
no
Repair by MT possible?
STEP 7 Endoscope to Medical Technology (MT)
yes
Leakage of endoscope?
Transfer form
yes
no
Repair performed
STEP 8 Manually brush channels
STEP 8 Suck out and/or flush channels
STEP 8 Disconnect leak tester
STEP 8 Wipe off the exterior of the endoscope
Registration of patient, doctor, and endoscope ID
yes
STEP 9 Place in disinfector and enter registration information
STEP 9 Add utrasonically treated spare parts to basket
no
STEP 9 Start automated leak testing, cleaning and disinfection
Repair by MT possible?
STEP 7 Endoscope to MT
yes
Leakage of endoscope?
yes
Transfer form
STEP 10 Check tubing, and such, after process
no
yes
no
STEP 10 Remove endoscope
Solvable by employee?
Known cause?
no
STEP 10 Release?
4 hours limit exceeded without drying
yes
< 4 hours reuse: mark as disinfected
STEP 11 Dry endoscope in drying cabinet

Figure 3 – *Primary process cleaning and disinfection flexible endoscope*

STEP 1 - Preparation of the endoscope before use

- All handling of a disinfected endoscope should be carried out with disinfected hands, possibly with gloves;
- Remove the endoscope from the drying cabinet or washer-disinfector (in case the endoscope is used within 4 hours). NOTE Release:
  - In case of an endoscope from the washer-disinfector, it should be indicated on the washer-disinfector that the endoscope completed the disinfection process without faults
  - When using an endoscope from the drying cabinet, the expiry date should not be passed[6]
- Place appropriate valves and caps.

STEP 2 - Transport of disinfected (dry) endoscope

- Place the endoscope on a new fibre mat (or otherwise protected against damage due to movement) in a clean dust-free container, that is closed (with the use of a cover, dust cover / plastic cover or comparable);
- The container must be clearly marked or sealed, indicating that the endoscope is disinfected;
- The container is marked with the expiry period, taking into account whether or not it is properly dried and transported to the examination/ endoscopy unit.

When using the endoscope on a patient gloves should be worn. During the endoscopy, all general precautionary measures, as recommended by the WIP, should be used. Used materials and liquids should be applied according the Spaulding principle[7].

STEP 3 - Pre-cleaning in the endoscopy room by the operator

Directly after endoscopy, the following operations should be performed while wearing gloves:

- Suck up clean water with the use of the suction and biopsy channel; [8]
- Continue sucking until a clear fluid is visible as output;
- Rinse and blow through water / air channel (with use of valve);
- Wipe off the exterior with an unsterile gauze;
- Set the friction controls of the endoscope in a neutral position (free);
- Disconnect the endoscope and bring it to the decontamination room. In case the decontamination room is not directly adjacent to the endoscopy room, the endoscope must be transported in a closed container (identified as contaminated transport);
- Place protective cover subsequently after completion of the examination;

[6] The WIP indicates a “shelf life” of a year if the endoscope is dried properly. The SFERD believes that this ignores risks occuring during storage, during the opening and closing of doors to move the endoscope in and out. The SFERD recommends a period of one month, also regard to the advice to clean and disinfect the drying cabinet every month.

[7] In 1968, Spaulding developed a cleaning, disinfection and steilisation scheme for medical devices base don the infection risk for patients. Spaulding assumed three categories: critical, semi-critical and non-critical. Critical means that a high risk of infection for the patient excists if the medical device is contaminated with microorganisms. In this case, sterilisation is required. In semi-critical risk, the risk of infection for the patient is lower and disinfection of medical devices is sufficient. For non-critica risk, cleaning is sufficient.

[8] If cleaning fluid is used instead of water, it should be transparent in order to assess the brightness of the output.

freely provided the SFERD is listed as the author

- Make sure that the identification of patient, physician, and endoscope ID are provided.

STEP 4 - Transport of an used endoscope

- Put the used endoscope back into the container on the fibre mat (or otherwise protected against damage due to movement);
- Clearly indicate on the container that the endoscope is used and potentially contaminated. For example: the lack of seals on the container characterises the endoscope as contaminated;
- Transport the container to the decontamination room;
- Directly present the container for the manual pre-cleaning and machine disinfection.

STEP 5 - Preparations before cleaning and disinfecting of the endoscope

Requisites

For personal protection:

- apron, not water permeable;
- gloves;
- mouth / nose mask;
- safety goggles or splash shield.

For the cleaning process:

- A suitable detergent for manual pre-cleaning, compatible with the detergent and disinfectant that are used in the washer-disinfector. Exposure time, concentration, and temperature are applied according to the instructions of the manufacturer;
- Gauzes or fibre cloths;
- Various channel brushes (compatible to the diameter work channel, preferably single-use); [9]
- Tools to rinse / blow channels, such as:
- Air / water pistol;
- Luer lock syringes;
- Tube water jet channel(depending on type and brand of scope);
- Tube elevation channel (depending on type and brand scoop).
- Leak tester;
- Transport containers clearly labelled ‘contaminated’ or ‘clean’;
- Detergents and disinfectants for transportation containers or a container washer-disinfector.

Execution:

- Fill up the clean sink with detergent (concentration and temperature according to the recommendations of the manufacturer);
- Put the fibre mat on the counter bench;
- Remover the valves and distal caps.

[9] The SFERD strongly recommends the use of single-use brushes, adjusted to the diameter of the chanel. The brushes can be used for half a day for several endoscopes of the same type. With this advice, the SFERD aims an adequate pre-cleaning, which is better achieved by using good quality brushes, instead of the sterility of used brushes. Reusable brushes can be used half a day when disinfected, but often show a quick reduction in quality due to the disinfection process.

STEP 6 – Leak testing of the endoscope

- The endoscope is placed on a fibre mat, with the controls facing up;
- Turn on the leak tester;
- Connect the leak tester to the connection at the light conductor plug on water cap of the endoscope (check the pressure);
- The cardan envelope slowly swells;
- Immerse the endoscope entirely in the sink filled with detergent, in which the entire length of the endoscope can be submerged;
- Wait for at least 1 minute, until the pressure is raised sufficiently;
- Check the endoscope for leakage, while wagging the tip;
- In case of leakage of the endoscope, see STEP 7;
- In case there is no leak of the endoscope, manually perform the pre-cleaning: see STEP 8;
- The endoscope should be removed from the fluid and put on a fibre mat, always with a still functional and connected leak tester pump;
- Turn off the leak tester and pull the connection a little back from the device in order to vent the endoscope[10];
- Wait for at least 1 minute, until the pressure is decreased completely;
- Disconnect the leak tester from the endoscope.

STEP 7 - Handling of a damaged endoscope

If an endoscope does not function properly, but there is no leak, then this endoscope can be disinfected and dried normally. Subsequently, the malfunction is reported to the Medical Technology / Clinical Physics. An endoscope with leak cannot be disinfected and may contaminated with pathogenic microorganisms. The endoscope should be treated as follows before presenting it for repair:

- Clean the not yet disinfected endoscope on the exterior and wipe it off with 70% alcohol;
- Dry the channels (mechanically or manually). If the endoscope is shipped “wet”, this can cause major damage to the endoscope;
- Provide the endoscope with a label marked "contaminated";
- The user fills in the conveyance form (see example: appendix 2);
- The technician handles the endoscope with gloves, possibly with safety goggles and mouth- nose mask;
- The technician wraps the endoscope in film and carries it in a transport case. On and in the case it should be clearly stated that the endoscope is contaminated;
- After repair and before usage the endoscope should <u>always</u> be reprocessed.

STEP 8 - Manual pre-cleaning of the endoscope

- Make sure that the channels are filled with detergent before brushing;
- Brush the biopsy/suction channel in three directions:
  - From the suction valve distally;
  - From the biopsy valve distally;
  - From suction valve to the connector;
  - There are endoscopes in which there are other additional channels that need to be brushed.
- Suck water or detergent through all channels;
- Rinse the jet channel with water or detergent solution;
- Where applicable rinse the CO_2 channel with water or detergent solution;
- Where applicable rinse the elevator channel using a 2ml syringe filled with water or detergent solution;

[10] Action depends on the type of leak tester

freely provided the SFERD is listed as the author

- Wipe the exterior off with a gauze;
- Brush the control knobs of the operating system and the distal end;
- Brush the valves (see section 5.2);
- Remove the endoscope from the sink;
- Place the endoscope on a fibre mat.

STEP 9 - Automated cleaning en disinfection in the washer-disinfector

- Open the washer-disinfector preferably with a foot or knee switch;
- Position the endoscope into the washer-disinfector while wearing gloves;
- Connect the leak tester of the washer-disinfector;
- Connect the channel irrigation tubes to the channels of the endoscope (according to the instructions of the manufacturer of the washer-disinfector), use the appropriate set of tubes, suitable for the endoscope;
- Pay attention to the additional channels and connect these;
- Check for any kinks in the tubes;
- Where necessary remove any unused tubes, for this see the manual of the supplier;
- Place the valves, distal caps and such in the washer-disinfector, after ultrasonic treatment (see section 5.2);
- Remove gloves and disinfect hands;
- Close the door of the washer-disinfector;
- Choose the appropriate cycle, according to the instructions of the supplier;
- Register the required information (automatically or manually):
  - date + time;
  - identification number of the washer-disinfector ;
  - patient information;
  - identification number of the endoscope;
  - physician;
  - endoscopy nurse/-assistant or CSA employee.
- Start the cycle;
- If the washer-disinfector interrupts the cycle due to an error, such as ‘endoscope leak‘ or ‘disconnection’, the manufacturer's instructions should be followed;
- Call in the help of the Medical Technology / Clinical Physics in case of repeated error messages.

STEP 10 - Release of the flexible endoscope after disinfection

- Check the display of the washer-disinfector to see whether the disinfection process has been completed without errors;
- Open the washer-disinfector with disinfected hands (possibly with gloves) or by means of a foot switch;
- Check whether all tubes, caps, and channel separators are still connected;
- When all conditions are met, then the endoscope can be released. Mark the release on the 'release form flexible endoscope’ (see appendix 13) or in an automated manner;
- When not all conditions are met, then the problem must be solved and the disinfection process be repeated;
- When used within 4 hours after disinfection, the transport containers should be provided with a label on with the expiration time is noted. When the endoscope is not used within the prescribed time, it must be presented for disinfection again. Prior to transport the endoscope may be dried with compressed air both on the inside and outside.

STEP 11 - Process of drying the flexible endoscope

- If the endoscope is not directly used, place in the drying cabinet;
- Connect all channels of the endoscope according to the manual of the supplier. The drying takes 30-120 minutes, depending on the type of drying cabinet;
- Place the valves and other removable parts in a wire basket in the drying cabinet;
- Set the drying time according to the instructions from the supplier;
- After completion of the drying process and verification of the process parameters and approval, the endoscope can be released;
- After completion of the drying procedure, the endoscope (and the valve and other spare parts) can be stored indefinitely in a drying cabinet or dust free storage cabinet, according to the WIP. If the drying and storage cabinets are in the same area as the area where pre-cleaning of endoscopes takes place, the maximum storage time is reduced to a month.[11]

Remarks:

- In case the drying process of the endoscope is not completed, it needs to be presented for disinfection again, if not applied within 4 hours.
- In case of a not properly functioning drying cabinet, or in case it reports errors, the Medical Technology / Clinical Physics should be called for help and the (not adequately dried) endoscope should be handled with a maximum expiration time of 4 hours.
- The drying cabinet should be validated, as is stated in chapter validation
- It is recommended to include the drying process in the process / time registration.

STEP 12 - Reprocessing after office hours

- Directly after use, the first pre-cleaning takes place at the endoscopy room, as is described in STEP 3;
- This is followed by the pre-cleaning as described in STEP 8;
- As soon as possible, the pre-cleaning is followed by machine cleaning and disinfection.[12]

Suggestion

If qualified personnel are present, the endoscope can be disinfected automatically. The endoscope remains in the washer-disinfector until the next workday. The endoscope must be disinfected again, before being taken out of the de washer-disinfector the next day.
ATTENTION: this is not possible in case of a pre-setting of thermal disinfection with the use of a time switch!

Further studies on time(s) between use and disinfection has not been conducted and is recommended.

[11] In connection with the increased risk of recontamination of endoscopes by frequently opening of the drying or storage cabinet, a shelf time of one month is recommended. In addition, is is advised to clean the cabinet every month.

[12] The SFERD has identified how much time one sets for this in Dutch hospitals. The average time was 4 hours. With regard to this time, on the one hand is referred to the WIP advice for the maximum shelf time of disinfected endoscopes whithout drying and on the other hand to experiences with drying of organic material (microorganisms) on instruments.

freely provided the SFERD is listed as the author

STEP 13 - Loan flexible endoscopes and accessories[13]

- Principal (endoscopy department and / or Medical Engineering / Clinical Physics) places loan order[14] for users at the competent department of the institution;
- When applying for the order, the conditions of the supplier and documentation regarding technical information and cleaning and disinfection are required;
- Principal informs the involved departments (e.g.: CSA, DSRD and Medical Engineering / Clinical Physics) about the endoscope and accessories that are requested and the date and time of delivery, appliance, and return;
- User within the institution can schedule the examination only if the conditions for adequate cleaning and disinfection[15] have been met;
- Receipt and check of the endoscope and / or accessories within the institution at the department Medical Technology / Clinical Physics[16] and subsequently at the department for cleaning and disinfection;
- Loan endoscopes should be "returned" in the washer-disinfector, so that the appropriate specifications of the endoscope are saved in the washer-disinfector ;
- Cleaning, disinfection, and possibly sterilisation by the department concerned;
- Delivery of the endoscopes and/or accessories to the user;
- After use, return for decontamination as soon as possible. [17]

Explanation

Documentation by the supplier:

When offering the endoscope or accessories, it is always assumed that this is the first time it is offered. In case of a repeat, it should be reported that all documentation already is in possession of the departments concerned.

Documentation that should be provided by the company, according to EN-ISO 17664 [ref 39]:

- identification of the endoscope;
- cleaning, disinfection, and possibly sterilization protocols on behalf of loan packages;
- service regulation and regulation functionality test;
- decontamination declaration.

Receipt of the endoscopes / accessories, routing and verification

- the endoscope and / or accessories must be delivered in a closed transport packaging at Department of Medical Engineering / Clinical Physics at least 1 day in advance of the scheduled intervention;
- the endoscope is entered in the registration system of the institution by the Medical Technology / Clinical Physics;
- the Medical Technology / Clinical Physics is responsible for the transportation the department concerned;

[13] The same standards apply to both a loan disinfector and e new disinfector.

[14] Loan/lease: for use in patients during a given period, received by order number in the organisation. On approval: exclusively serving assessment, not in combination with use in patients / trial placement, etc.

[15] Compatibility is determined.

[16] Endoscopes should be registered with serial number and period of stay in the institution.

[17] Decontamination: proper cleaning and disinfection with a validated process that leads to a medical device that can be further supplied safely. If this condition cannot be met, consultation with the supplier is necessary.

- the supplier should keep a logbook of the endoscope that contains the decontamination declarations and the history of the instrumentation which should be accessible to the user on request;
- the supplier declares that the materials are decontaminated at the delivery of the endoscopes to the institution. He cannot make use of the certificate issued by a previous user.

Return by Medical Technology / Clinical Physics
- if the endoscope is cleaned and disinfected immediately after use, it is ready for dispatch to the supplier within 1 working day, including the issue of decontamination form (see example: appendix 3);
- the loan endoscope should be registered at the Medical Technology / Clinical Physics when returning it to the supplier.

STEP 14 - Deviations from the primary process of channel less endoscopes

The risk of transmission of microorganisms is considerably greater when using endoscopes with channels, compared to channel less endoscopes. This does not mean that these endoscopes can be reused without adequate cleaning and disinfection. The WIP prefers an automated cleaning and disinfection process regarding endoscopes without channels.
When using an endosheath, there is no indication for cleaning and the endoscope can be disinfected with 70% alcohol or other disinfectant approved for this purpose after removal of the sheath, as described in the WIP guideline. Thus, without use of the endosheath there is always an indication for automated cleaning.
A very exceptional reason for manual cleaning can be failure of equipment by a power cut.

In short, this means that the channel less endoscopes that are used with an undamaged endosheath can be disinfected after use with 70% alcohol with a contact time of minimally 30 seconds. The channel less endoscopes are transported to the decontamination room (in main building) where disinfection takes place, at the end of the program. This helps to ensure that the scopes are automatically tested for potential leaks with use of the leak tester in the washer-disinfector after every endoscopy program. The transportation of the scopes should take place in closed transport containers that can be cleaned and disinfected properly. Since the chance of a look-back procedure is so low, or it only holds one program in case of leakage of the scope, a track and trace registrations is deemed unnecessary.

The scope is stored dry in a storage cabinet or otherwise dust-free storage after disinfection. The drying of the scope occurs by air-drying it after manual disinfection with 70% alcohol. In case the scope is not retrieved dry from the machine after automated disinfection, it is advised to wipe off the scope with a gauze with 70% alcohol when removing it from the disinfector, so that air-drying is advanced.

STEP 15 – Replacing the detergent and disinfectant containers

Required materials:
- detergent and/or disinfectant, compatible with the endoscope and washer-disinfector;
- gloves;
- mouth / nose mask;
- apron;
- safety goggles

freely provided the SFERD is listed as the author

Procedure:
- Observe the prescribed safety precautions; see instructions washer-disinfector and safety information sheath on chemicals;
- The container with detergent and / disinfectant is replaced according to the identification given by the washer-disinfector;
- Take a new container from the stock cupboard. The types of containers to be used are recognisable, in such a way that only one type of detergent or disinfectant encloses the chemicals in a specifically shaped or coloured container. This will prevent exchange of chemicals belonging to suppliers with a wide delivery range of the same containers;
- Replace the container; pay attention to the correct colour coding at the connection. Explicitly read the labelling in your language;
- A check should be performed by the second person, when the containers are entirely connected, unless the check runs automatically.
- Register in the logbook: date, time, name of the replaced agent, name of the washer-disinfector, in case this does not run automatically it shall be signed by two individuals.

Remarks:
- Mix-up of containers results in insufficient cleaning and disinfection of the endoscopes.
- Use of not-compatible chemicals can lead to damage to endoscopes and washer-disinfector.
- The detergent and disinfectant used for manual reprocessing of endoscopes should be standardised at organisational level.
- Do not transfer residuals into the new containers.
- The containers with residual disinfectant should be closed and processed according to the hospital regulations.

STEP 16 - Self-disinfecting of the washer-disinfector

Most of the washer-disinfectors are equipped with a self-disinfection program. This program is performed to remove a possible bio film.
During the self-disinfection, internal parts of the machine will be reached that are not disinfected during normal use. The procedures are based on thermal disinfection.

Procedure:
- Check whether the washer-disinfector does not contain an endoscope and set the self-disinfection program. The self-disinfection program of the washer-disinfector should be applied according to the regulations of the supplier. At least weekly, preferably after the weekend (if consultation hours start on Monday);
- Certain types of washer-disinfectors are equipped with rinse water filters that need to be removed during the thermal self-disinfection. The supplier of the rinse water filters prescribes a disinfection and sterilisation procedure in case of prolonged and possibly uninterrupted use of the filters. After this procedure, the filter should be tested with the use of an integrity test, also known as a bubble point test.

Note:
The SFERD assumes that sterilisation can only be effective if this treatment is preceded by adequate cleaning and disinfection. The rinse water filters cannot be adequately cleaned, disinfected, and dried in the opinion of the SFERD. Therefore, the sterilisation process of these filters cannot be validated. Next to the physical problems that are involved with the construction, there are other issues. The filters turn out to

trap metal particles that obstruct the filter bed when in function. These particles will lead to damage that can harm the subsequent application during sterilisation. The SFERD advises to follow the recommendations of the manufacturer of the disinfector. Deviations of the procedure should only occur when substantiated and argued. In case of deviations from the prescribed procedures, the liability of the manufacturer may expire. The washer-disinfector remains substantially hot during a considerable time, so that a cooling period in necessary. In the meanwhile, the endoscope disinfection cannot take place. This needs to be taken into account when planning the thermal self-disinfection.

STEP 17 - Maintenance of the washer-disinfector

According to the manual, the Medical Technology / Clinical Physics in consultation with the DSRD, declares the type of maintenance that is required. Afterward, the responsibilities for this maintenance can be divided by at least the DSRD and the Medical Technology / Clinical Physics. The supplier recommends that the user performs frequent checks and the user maintenance on the washer-disinfector. The performed checks and maintenance should be logged; the form 'Maintenance of the washer-disinfector' can be used as an example for this (see appendix 4).

The form is saved per washer-disinfector in the logbook. By checks and maintenance is meant, among others:
- commencement of the self-disinfection cycle of the washer-disinfector minimally once a week;
- daily check for proper connection of detergent and disinfectant;
- daily check for (defect) connection tubes;
- daily check for (defect) O-rings;
- daily cleaning of control panel and handles;
- daily cleaning of (exterior) washer-disinfector;
- weekly cleaning of the strainer in the chamber drain;
- softening of the washer-disinfector (as soon as the washer-disinfector indicates this; frequency depends on the hardness of the water used).

These checks are also considered as part of the validation; see section 10.6-10.9.

5.2 Cleaning, disinfection, and/or sterilisation of accessories

Accessories that are used during endoscopy can be divided into four groups:
1. Accessory instruments used during endoscopy;
2. Rinse systems;
3. Endoscopy-accessories;
4. Accessories used during cleaning process;

In case the accessories directly contact the sterile tissue during endoscopy, these need to be sterile. The prescribed method for the four groups is described below:

Group 1: Accessory instruments used during endo-therapy
- These instruments directly contact the sterile tissue during the endoscopy;
- The application of single-use accessories is preferred;
- Reusable accessories should be sterilised. In case of usage of an irrigation system, sterile water should be used.

Group 2: Rinse systems
- Sterile water bottle is filled with sterile water and should be renewed daily;
- Use of single-use bottles is preferred;
- Reusable bottles should be sterilised.

freely provided the SFERD is listed as the author

Group 3: Endoscopy-accessories

- This group of accessories does not directly contact the sterile tissue, but there is a major chance of severe contamination with tissue and bodily fluids;
- Preferably the single-use accessories are used;
- Reusable accessories are preferably sterilised;
- Reusable valves should be brushed both in open and closed position.
- In this way, as much contamination as possible is removed. Afterward, they will be placed in an ultrasonic bath, the washer-disinfector, and the drying cabinet.

Group 4: Accessories used during cleaning process

- The instruments do not directly contact the patient;
- These accessories are preferably single-use;
- Reusable brushes should be rinsed with water directly after use. Thereafter they can be cleaned and disinfected with the endoscope.

Table 1 – *Accessories and their respective means of disinfection or sterilisation*

Group	Types of accessories *	Ultrasonic bath and machine disinfection	Machinated disinfection only	Sterilisation[18]	Single Use
1	Biopsy forceps, loops, ERCP materials and irrigation equipment			X	X
2	Water rinse bottle and hose			X	X
3	Valves, caps, and mouth piece**	X			X
4	Cleaning brushes, water jet channel tubes.		X	X***	X

NB: - single-use accessories are always preferred over reusable ones.
- Savary probes can be mechanically disinfected after manual pre-cleaning, in case the supplier provides a compatibility declaration.

* = accessories that are not resistant to disinfection or sterilisation may once be used and should be discarded after use

** = valves, mouth piece, and such are treated as the accompanying endoscope

*** = if material is resistant to sterilisation

Ultrasonic Cleaning

Ultrasonic cleaning is recommended for all reusable accessories with the exception of plastic materials.

Requirements:

- Ultrasonic bath;
- Detergent, compatible with ultrasonic treatment and the accessories to be cleaned;
- Gloves;
- Water.

[18] Sterilisation is always preceded by mechanical cleaning and disinfection.

Procedure:

- Fill the bath with water to the lowest indication for the minimal quantity of water; top line is the designation for maximum quantity of water;
- Fill up the required amount of detergent to reach the prescribed concentration and mix the liquid well;
- Wait 5 minutes before placing the materials placed in the bath after turning on the ultrasonic bath, because the water is degassed during those first five minutes. Dissolved gases, normally present in fresh water, reduce the ultrasonic cleaning effect;
- Accessories should first be brushed (valves both in open and closed position) and rinsed immediately after use to prevent biological remainders to cake or dry out;
- Materials should be placed in an ultrasonic bath with closed by a cover for a duration of minimally 5 minutes;
- The ultrasonic bath is closed, because due to the vibrations aerosols can develop which are potentially contaminated with micro organisms;
- The materials are removed from the bath, rinsed under the tap, and placed in the basked after termination of the ultrasonic treatment;
- Cleaned materials are washed and disinfected in the washer-disinfector, or for mechanical cleaning and thermal disinfection transported to the CSA;
- Ultrasonic fluid should be refreshed minimally once per shift and in case of visible contamination.

5.3 Disinfection of TEE transducers

The currently used TEE transducers are not suitable for cleaning and disinfection. Therefore, a manual cleaning and disinfection is necessary, while care should be taken of a universal, clear, and verifiable approach. The transducer is a very fragile instrument that is particularly susceptible to buckling and bending. Proceed as follows:
ATTENTION: NEVER IMMERSE THE ELECTRONIC PARTS (THE CONTROL STATION) OF THE TRANSDUCER!

Registration

Register the number of the transducer, the patient number, the date and time of the endoscopy, the name of the doctor and the disinfection employee.

Cleaning

Note: In case the transducer is used with an intact sheath and is not visually contaminated, the cleaning step can be omitted.

- Perform adequate hand hygiene;
- Wear gloves;
- Check the entire transducer for contamination and irregularities;
- Make a solution of detergent in water in a container;
- Clean the transducer with a single-use cloth or gauze which is immersed in the solution. Work from clean to contaminated (repeat this 1 time);
- Properly wrench the cloth , which is immersed in a portion of the solution again, and use it to clean first the control panel and thereafter the transducer (work from clean to contaminated);
- Rinse the transducer with water so that all chemical residues have disappeared;
- Again check the transducer carefully to see whether all contamination has disappeared visually and whether the chemical residues are resolved.

freely provided the SFERD is listed as the author

Disinfection

- Use 70% alcohol or a disinfectant that is approved by the supplier;
- Perform adequate hand hygiene;
- Wear new gloves.

Method1
- Drench a cloth in 70% alcohol;
- Wipe off the transducer with a cloth or gauzes drenched in 70% alcohol. The alcohol should have a contact time of 30 seconds on the transducer (use timer);
- Air-dry the transducer;
- The transducer can be used again only after the alcohol is fully evaporated.

Method 2.
- Use the method as is described by the supplier of the disinfectant. Pay attention to the prescribed concentration, contact time and rinsing procedure to remove the disinfectant.

Storage and transportation of the transducer

Store the transducer in a way that contact with contaminated surfaces is impossible, e.g. hanging in a holster / cabinet freely. The transducer is very vulnerable so it should be protected against dust and falling: the location of the holster must be chosen in such a way that this is prevented.

The transducer must be protected for transportation. Transportation can best take place in a container, padded with a fibre mat or cloth large enough to accommodate the transducer without excessive bending. Hanging it in a narrow pipe properly protects the transducer if the pipe is only used for clean probes. In case the transducer is stored in a case, the transducer needs to be disinfected before the examination.

The transportation of a contaminated transducer should occur in a recognizable closed container, labelled as contaminated. In addition, the container should be cleaned and disinfected after cleaning and disinfection of the transducer.

5.4 Installation of a washer-disinfector

An installation check is performed by the supplier in consultation with the Medical Technology / Clinical Physics before putting the washer-disinfector into use, regarding the following items.

General facilities

There must be at least a water supply (including filters), a sewer connection, electricity, vaentilation connection, and a network connection in the room.

Instrumentation

- Testing and if necessary calibration of:
  - sensors for temperature, pressure, and flow;
  - disinfectant dosing system;
  - detergent dosing system.
- technical validation (see section 10.5 validation);
- Assemble logbook per washer-disinfector, note:
  - process counter;
  - Inventory information of the machine;

- preventive and corrective maintenance;
- process faults;
- replacement of parts;
- process cancels;
- replacing of the detergent and disinfectant containers;
- validation (reference to validation report);
- release declaration.

Microbiologically

- Microbiological validation (see section 10.7.3).

The reporting of the abovementioned items is carried out by the responsible department to the DSRD;
The assessment and functional release of the washer-disinfector is done by the DSRD (see appendix 5 release form);
The filing of the installation report (technical and microbiological) occurs under the responsibility of the DSRD.

5.5 Risk inventory and evaluation

The cleaning and disinfection of endoscopes is performed to prevent risks for patients. However, these procedures possibly involve other risks. Both the supplier of the detergent and disinfectant and the heads of the involved departments are obliged to consider this. Risks can be divided in the following categories:

- Risk for employees
- Risk for endoscopes and washer-disinfectors;
- Risk for the environment;
- Risk regarding chemical safety;
- Risk regarding microbiological safety.

Risks can be minimised by using general precautionary measures or specific measures that are applicable in a specific situation. Possible risks and required measures are described per category below.

Risks for employees

Activity	Risk	Risk restrictive measure
Transportation of contaminated endoscopes	Injury, contamination, and physical complaints	Clear working instructions, protective clothing, vaccinations according to hospital policy, and appropriate occupational attitude
Manual pre-cleaning of contaminated endoscopes	Injury, contamination, contact with chemical fluids (through skin, mucous membranes, or inhalation), and physical complaints	Clear working instructions, protective clothing, vaccinations according to hospital policy, and appropriate occupational attitude

freely provided the SFERD is listed as the author

Loading and unloading of washer-disinfector	Injury, contamination, contact with chemical fluids (through skin, mucous membranes, or inhalation), contact with electricity, and physical complaints	Clear working instructions, protective clothing, vaccinations according to hospital policy, proper ventilation of the workspace, extraction of the washer-disinfector, regular maintenance, and appropriate occupational attitude
Replacing detergent and disinfectant containers	Contact with chemical fluids (through skin and inhalation)	Clear working instructions, protective clothing, mask, proper ventilation of the workspace, and appropriate occupational attitude
Storage clean endoscopes Ultrasonic activities	Injuries, physical complaints Hearing loss over time	Gloves, appropriate occupational attitude Noise level below 80 dB, hearing protective measures

Risk for endoscopes and washer-disinfectors

Activity	Risk	Risk restrictive measure
Transportation of (contaminated) endoscopes	Damages	Clear working instructions, protective transportation containers
Manual pre-cleaning of contaminated endoscopes	Damages, leaks, corrosion, bio film	Clear working instructions, appropriate detergent/materials, mechanical cleaning, thermal self-disinfection
Loading and unloading of washer-disinfector	Damages, failures, leaks of the endoscopes and washer-disinfectors	Compatibility check, clear working instructions, appropriate detergent/materials, preventive maintenance
Storage clean endoscopes	Damages	Protective transportation containers, proper drying cabinets, proper storage cabinets

Risk for the environment

Activity	Environmental Risk	Risk restrictive measure
Disposal of chemical waste	Improperly disposing and leaking of chemical waste	Clear working instructions, special containers, and disposal procedures
Discharge to sewer	Improperly discharging chemical waste	Clear working instructions, discharge permit

Risk regarding chemical safety

Activity	Risk	Risk restrictive measure
Discharge of chemical waste	Improperly disposing and leaking of chemical waste	Clear working instructions, special containers, and disposal procedure
Changing detergent and disinfectant in washer-disinfector	Unintentional spillage and leakage of detergents and disinfectants, improperly disposing	Clear working instructions, proper storage of detergent and disinfectant, special containers, and disposal procedures
Ventilation of the area in which the washer-disinfectors are set up	Unintentional leakage of hazardous vapours	Proper ventilation, use, and maintenance of suitable filters

Risk regarding microbiological safety

Activity	Risk	Risk restrictive measure
Transport contaminated endoscopes	Contamination employees, cross-contamination other materials	Clear working instructions, closed transportation containers, sufficient working space, good logistical organisation**
Discharge contaminated material	Contamination employees, cross-contamination other materials	vaccinations according to hospital policy, clear working instructions, (proper use of) waste containers, good logistical organisation

** including: separation of clean and contaminated materials

5.6 Traceability of endoscopes and patients

The IGZ prescribes the hospitals to use a system, which contains traceability information about which endoscopes is used for which patient, by who, and in which washer-disinfector the endoscope is cleaned and disinfected.

Tracking & Tracing

Tracking and tracing is the registration of the successive data that guard the efficacy of the disinfection process. Preferably, registration of the endoscopy and disinfections processes takes place automatically.

Required measurement data and registrations:

- Entry of the process number associated with date and time of the disinfection process;
- Entry of serial number of the washer-disinfector and the section (container left or right, place 1,2,3, or 4, etc);
- Entry of endoscope serial number per section or place;

freely provided the SFERD is listed as the author

- Entry of patient identification (patient number) of the used and to be disinfected endoscope per section or place;
- Executive doctor handling the scope per section of place;
- Executor of cleaning & disinfection per section or place; person who places the endoscope in the washer-disinfector and person who takes the endoscope out of the washer-disinfector after the cleaning and disinfection process (=person who releases the endoscope to for safe reuse);
- Entry of an effective /interrupted cleaning & disinfection process per section or place with the entry of measurement data, such as:
- pressure measurements (including leak test and continuous pressure monitoring for connection controls and flow);
- temperature measurements;
- duration of phases of Cleaning process, Disinfection process, and Drying;
- starting time, finishing time, duration of the process, and possibly the duration of various other phases of the process.

The data that should be registered per work process / workspace is presented below:

- The performance of the endoscopy:
  - patient information;
  - physician;
  - identification number and charge number of the endoscope.
- The loading and connection of the endoscope in the washer-disinfector :
  - patient information;
  - identification number endoscope;
  - identification number washer-disinfector including position of connection (left / right, top/bottom);
  - name of the operator.
- Release of the endoscope:
  - Identification number endoscope;
  - Identification number washer-disinfector;
  - name of the operator.

Retention period registration data

There are no legal terms postulated for the retention of technical data on cleaning and disinfection. For sterilisations, the Decree sterilised medical devices in hospitals [ref 43] states that protocols of a lot of sterilisation lot “shall be preserved at least 6 months”.
For sterilisations for third parties, there is an established retention period for sterilisation protocols of 5 years in force [ref 44].
Retention periods of 6 months are regarded to be on the short side within the work field, since there is a chance that presentation of symptoms of infections due to patient examination can manifest itself after 6 months.
The SFERD recommends a retention period of 5 years for the technical data on cleaning and disinfection. This allows an organisation to demonstrate that the manifestations of infections in a patient in all probability cannot / will not have been caused by inadequate endoscope disinfection.
This retention period includes the look back periods, which are held in the evaluation of incidents regarding inadequate cleaning and disinfection procedures of endoscopes.

It is recommended that a back up of all available data is made periodically. It is undesirable that the data is only stored locally on a workstation, the data must be managed centrally (on a network).

6. APPRECIATION BY CUSTOMERS

6.1 Patient safety

Within the EFQM model (see figure 1), the appreciation by cooperating partners, customers, and suppliers is of great importance for successful operation of the organisation. Partners are external organisations with a close and / or long-term collaboration. These can be suppliers and / or buyers, sometimes in changing roles. It is necessary to know how they appreciate products, service, and cooperation. What is their opinion about the products, service, or cooperation? Does the organisation have insight into the arguments for why one uses its service or not? And what can the organisation expect from them in the future?

Patient satisfaction can be investigated. There are investigational methods available for this and there are examples of questionnaires. To match the service to the expectation of patients, organisation-wide creative initiatives can lead to the increase of the patient supply. This can result in an increased demand of examinations requiring the use of flexible endoscopes.
Nice decoration with an eye for colour and function in combination with a friendly and discreet treatment gives the patient confidence to be in good hands. Indications that the requirements laid down in guidelines and standards are met can contribute to a justified sense of patient safety.
Transparency in the form of leaflets about examinations that the patient might undergo, will reassure the patient and will help to ensure that the patient can be examined in a relaxed ambience.
Staff and other resources should be available to allow the patient to communicate complaints or suggestions about the patient experience both verbally and in writing. The patient must be convinced that, when reporting complaints or suggestions, his points are at least considered when assessing possible improvements of future patient care, audits or emergency response exercise.

6.2 Turn-over / availability endoscopes

Within a team of an endoscopy department, the medical specialist can be seen as a customer with demands, rights, and duties. In the treatment of the patient, the specialist should be able to assume that the correct endoscopes are present at the right time. The decontamination cycle should be aimed at having the endoscope available for patient examination in time.
It is up to the specialist to make sure that the presented endoscope is properly cleaned and disinfected, so that patient safety is not at stake, as expressed in the guideline of the Order of Medical Specialists on medical equipment [ref 30.].

freely provided the SFERD is listed as the author

7. APPRECIATION BY HEALTH CARE STAFF

In this area of the EFQM model, it is reflected to what extend the organisation is of additional value to its employees. The appreciation by health care staff should be evaluated by means of staff satisfaction surveys. Based on the results of such surveys, an organisation can learn lessons to bind staff and interest them. New developments can lead to the expansion of tasks that can lead to different pay scale being applicable following an official assessment of the new activities (Function Appreciation in Health Care). Management has to create a balance between work, payment, development, and enough challenge for the employee. A positive motivation leads to more dedication and more effective performance of tasks.

Within the work field 'flexible endoscopes', it is of importance that employees are content and have a feeling of security, regarding both the employees themselves and the patients. This requires a description of the task to be performed within the organisation in a quality handbook of endoscopes. When performing a task based on a quality handbook, an employee can have the confidence to execute the necessary procedures in a proper and safe manner. Procedures are derived from guidelines and established in protocols based on local conditions. The protocols were established with support of the team and give direction to the daily operations. This allows procedures to be standardised, auditable and improvable. The protocols should also address the care of a safe working environment. In this context, the statutory registration of dangerous substances is met and care is taken for working conditions with regard to for example activities that involve noise and climate. To maintain the quality of working and labour conditions it is necessary that an organisation has access to the Medical Technology / Clinical Physics, a division Infection and DSRD. Good equipment should be used that meets the state of the art. This requires the willingness of a Board of Directors to invest in this.

8. APPRECIATION BY SOCIETY

The appreciation by society is an important factor in the quality of care within the Dutch hospitals. The development of performance indicators add to the improved transparency in healthcare. Media attention for the quality of healthcare is an important motive to consider the quality of healthcare of paramount importance. Incidents regarding cleaning and disinfection of endoscopes received considerable attention in the media. This led to image damage of the involved hospitals. Healthcare transparency leads to increased social pressure. This manifests itself among others in government-mandated targets, as stated in the Safety Management System (VMS). The patient safety is an important issue in the contemporary management of the hospitals.
Society demands the hospitals to safely perform endoscopic examinations and to provide openness of affairs, even if safety is only slightly at stake. This means that a hospital should have adequate resources for incident management. This should be aimed at on the one hand prevention of recurrence of incidents, and on the other hand, provide clear information about incidents and possible risks for the patient.

8.1 Incident management

Despite all the attention for proper cleaning and disinfection of flexible endoscopes, the possibility remains that an incident occurs. The steps that should be taken in incident management are established based on a risk assessment; in other words, based on the estimation whether the incident (possibly) causes an emergency. The aim of incident management, regarding incidents with flexible endoscopes, is to take immediate actions to prevent possible transfer of microorganisms through improperly cleaned and disinfected endoscopes and/or accessories. Moreover, the aim is to take measures to prevent such an incident in the future and to investigate whether patients/employees have been at risk of transmission of microorganisms.

In case of an incident, the prevailing procedure is used in the hospital. The head of the incident committee recommends the Board of Directors to assign an expert team if necessary, consisting of DSRD, medical microbiologist and/ or virologist, a representative of the department infection prevention, a representative of the Management / Board of Directors, a representative of Medical Technology / Clinical Physics, and a representative of the involved endoscopy department(s).

The expert team is responsible for:

- performing a further analysis of the nature and extent of the identified incident and the consideration of risks to patients and staff;
- informing the management, based on the findings;
- advising the management about the steps that should be taken and the measures to guarantee the patient and staff safety;
- establishing an evaluation report and establishing a prevention strategy to prevent such a situation if necessary;
- delivering internal – and if necessary external – reports (among others on behalf of the IGZ)
- identifying and analysing all necessary information;
- determining whether there really is an incident, based on all available information;

freely provided the SFERD is listed as the author

- advising the management about the measures that should be taken to guarantee patient safety, including temporarily stopping the endoscopic examinations.

8.2 Aspects on the application of incident management

The incident procedure is applied in an identified deficiency in the cleaning and disinfection process of endoscopes. The table below contains examples of possible incidents; however, this table is not complete. The DSRD makes a risk estimation of the incident, based on the report and in consultation with a doctor a risk estimation of the risk for the patient if necessary. Based on this assessment, the procedure below can be started.

Table 2 - *Examples of incidents*

inadequate cleaning and disinfection process of endoscopes and / or accessories
▪ inadequate pre-cleaning (e.g. channels are not brushed) ▪ use of wrong and/or expired chemicals ▪ working with wrong concentrations, exposure times and / or temperature ▪ contamination of the post-disinfection rinse water and / or culture fluid of the endoscope ▪ detection of fixed organic material in endoscope and / or washer-disinfector ▪ use of non-sterile accessories for invasive diagnosis / treatment
Inadequate transportation and/or storage of endoscopes
▪ insufficient drying of endoscope ▪ improper storage of endoscopes (e.g. in transport cases)
Contaminated / defective washer-disinfector
▪ contamination of tubes, containers, etc. ▪ contamination of the post-disinfection rinse water ▪ bio film in pipes, containers, etc. ▪ washer-disinfector used incorrectly (e.g. wrong programs) ▪ technical failure (detected during the validation or maintenance).
Design limitations and/or damages to the endoscope
▪ lumens too small and/or not accessible channels (not accessible for brushes) ▪ damage to endoscopes (with possible accumulation of organic material)
Insufficient execution of the cleaning and disinfection process
▪ omissions in the process by lack of expertise of staff ▪ incomplete process due to too high turnover rate / workload

8.3 Phases in the incident procedure

The following flowchart describes the different steps that are taken. It is possible that different steps are started and executed in parallel.

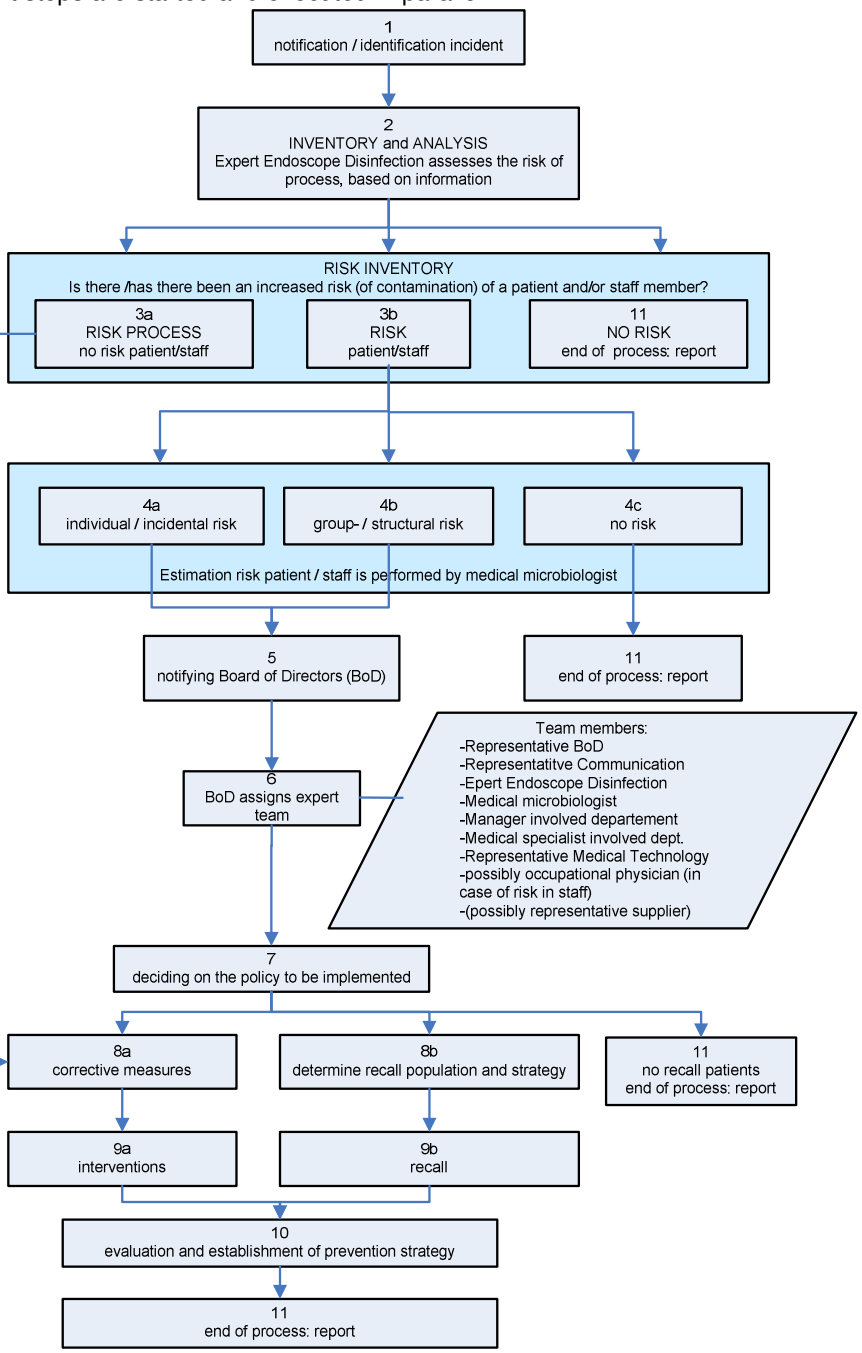


Figure 4 – *Action plan incident procedure*

8.4 Amplification on phases in the incident procedure

STEP 1 - Notification

The DSRD receives a notification based on:

- signals from staff, medical specialist;
- results of periodical controls (maintenance, validation, culturing);
- deviating process parameters of the automated cleaning and disinfection process;
- findings of production registration by means of tracking & tracing.

STEP 2 - Inventory and analysis

The DSRD identifies and analyses the notifications. The table in section 8.2 (examples incidents) can be used as a guide. In case the notification turns out to be 'merely' a deviation from daily practice, then this procedure will not be continued. An exception can be a structural abnormality in the daily actions.

STEP3 - Risk inventory

Based on the inventory and analysis the DSRD estimates whether there is/has been:
SCENARIO 1: Risk in the process
Omissions in the work process can lead to a risk for the patient and/or staff in the long term. These omissions should be included and controlled in protocols and/or work instructions. Patients and/or staff were not at stake due to these omissions; a recall of patient / staff is not indicated.

SCENARIO 2: Risk to patient and / or staff
In case of suspected or demonstrated risk for patient and/or staff, the DSRD directly contacts the medical microbiologist to further assess the risk (see step 4). Note that the risk does not always have to be of microbiological origin; there may be for example chemical hazards involved. In that case, a pharmacist / toxicologist and safety expert can be involved.

SCENARIO 3: No risk to patient and / or staff
The notification turns out to lack a risk for the process, the patient, and staff, after analysis. The procedure is terminated; the notification is reported.

STEP 4 - Risk estimation

The medical microbiologist, pharmacist / toxicologist, and safety expert can assess the risk together with the DSRD. The result of this estimation can have three outcomes, namely:

a. There is an incidental risk for one patient/employee. The deviation may already be present, but based on the inventory and analysis, the risk assessment can be limited to one individual. In this case, the procedure is continued.
b. There is a structural risk, which affected several patients and/or staff. In this case, the procedure is continued.
c. It is concluded that there is (was) no risk for patient and / or staff. The procedure is stopped here, the notification is reported.

STEP 5 - Notifiifying the Board of Directors

The DSRD reports the findings to the BoD and advises the president of the BoD to assign an expert team.

STEP 6 – Board of Directors assigns expert team

The representative of the BoD assigns an expert team; the team members are determined by the DSRD and medical microbiologist. Depending on the individual risk (Step 4a) or group risk (step 4b), the size of the team can be established. In case the employees have been at stake, the occupational physician will be part of the team.

STEP 7 – Deciding on the policy

The expert team decides about the policy to be implemented and advises the BoD on this. The following issues need to be addressed:

- can endoscopic examinations proceed without an increased risk for the patient and / or employee;
- should patients be recalled for examination, if the risk of hepatitis B, hepatitis C and / or HIV cannot be ruled out;
- should the incident be reported to the IGZ;
- should there be a press release.

In case the incident is caused by a malfunction of the equipment, the supplier will be contacted to be involved in the determination of the further investigation and strategy.

STEP 8 - Elaboration of decision making

A. *Corrective measures*
Establish measures to ensure that no further risk and establish measures to prevent incidents in the future.

B. *Recall-population and strategy determination*
- based on collected data, the period of risk and population at risk is established;
- based on the risk assessment, it is determined which investigations will be performed and when they will be performed;
- based on decision making the strategy with respect to the communication to patients, staff, and media is determined.

C. *No recall*
If the expert team decides a recall not necessary, the procedure is terminated here; the notification, estimation, and the decision-making should be reported.

STEP 9 – Actions based on the policy

A. *Interventions*
The established corrective measures are performed. The head of the department is responsible for the execution.

B. *Recall*
The recall is performed as established. The medical microbiologist is, due to the risk estimation of blood-borne diseases, responsible for the recall process. The involved medical specialist is responsible for the contacts with the patient(s). The occupational physician is responsible for the contacts with the employees (if they have been at stake).

C. *Communication*
Board of Directors and/or the department PR & Information is responsible for the communication with the media.

freely provided the SFERD is listed as the author

STEP 10 – Evaluation and establishment of prevention strategy

The course of the procedure is evaluated and reported to all involved parties. Based on this evaluation, possible improvements are formulated to prevent repeat of this incident in the future. The improvements can be included in the endoscope management plan. If necessary, the procedures are changed.

STEP 11 – Termination process: report

The DSRD reports on the procedure in a final report. This report is send to at least BoD, infection prevention committee, members of the expert team, and the IGZ if relevant.

8.5 Image damage on the institution

Every organisation delivers not only services to (members of) society, but also takes part of it. An organisation can show that it drew lessons from an incident and can therefore distance itself from the unfavourable situation before the incident. After all, the applicable examinations should be resumed in the interest of the healthcare according to the new quality standard. This new standard is established after demonstrable implementation of for example customised / or new equipment, increased expertise among practitioners, improved support in the organisation / by the supplier of the involved accessories, or changed procedures. Unreasonable expectations of society should be prevented: state what you do and how you do it. For cleaning and disinfection, there is high quality of disinfection, which should be in line with the type of instruments in relation to the field of application. The easily called term 'sterility' should be avoided. Communicate in internal and external media that you justify the necessary changes. Mention the remaining marginal chance of a risk compared to the time prior to the incident and that this is reduced to a standard accepted by the authorities (IGZ / WIP). Point out the effect of your quality management system and the role of audits in the near and longer term.

When managing responses from patients, the involvement of a confidential counsellor or contact person of a patient can be useful. Patients can file a claim to the organisation because of suffering, in the form of uncertainty or certainty about an infection caused by the incident. Handling these claims should be done in accordance with arrangements with any insurance companies of the institution.

Dealing with the media can be (partially) delegated to the department of Public Relations or Communication by the Management / Board of Directors.

9. RESULTS

Secured safety on behalf of the patient and staff. The patient should be able to count on a justified confidence in responsible care (IGZ adage). This care is achieved by:

- presence of an operational quality system to manage the process of cleaning and disinfection of endoscopes;
- presence of a structural process of quality assurance of which the formulated improvement points are executed;
- consideration of the following principles: applicable laws and regulations on quality assurance of cleaning and disinfection of endoscopes, such as the Quality Act of Healthcare Institutions [ref 40], Health Care Professions Act [ref 41], and the act on medical devices.

The Dutch Healthcare Inspectorate uses the guidelines of the Dutch Workingparty on Infection Preventionto assess the conditions of quality assurance of cleaning and disinfection of endoscopes. Following and applying the developments shall take into consideration the state of the technology. These should be considered to be directives for the continuous improvement process, particularly where new buildings or renovations come up. The staff, having the necessary expertise, should be given the opportunity to meet the previously mentioned requirements in the scope of good (healthy) working conditions, a stimulating work climate with expert attention to the environment.

freely provided the SFERD is listed as the author

10. IMPROVEMENT AND INNOVATION BY AUDIT & CONTROL

10.1 Performing audits

Next to the regular organisation audits (NIAZ), a yearly substantive audit should be carried out, in accordance with the IGZ advice, by the DSRD in collaboration with the Infection Control Department to assess rooms, facilities, equipment, logs, and test procedures at all endoscopy departments and the Medical Technology / Clinical Physics. This audit can be of general or thematic nature. An example of a general audit is provided in appendix 17 and 18. The results and possible recommendation proposals are reported to the management concerned.

10.2 Risk inventory and evaluation

Next to the requirement of regular audits on the quality of performing general procedures that concern disinfection of endoscope, the IGZ encourage periodic evaluation of the effectiveness of handling emergencies in combination with tracking and tracing. This requires the DSRD to devise a possible incident and to investigate whether patients involved in the look back process can be traced. The efficacy of the agreements on this within the institution should be evaluated for the available expertise of infection prevention, instrumentation, and management level. The improvement points defined in this process must be documented, as well as the performed STEPs and findings in the handling of the practice incident by means of a report.

This means:

- devising an incident;
- analysing the risk at instrumentational level / procedural / microbiological risk;
- handling the deviation so that no further risks are present;
- analysing the patients exposed to the risk-bearing agent;
- involving the required expertise for identifying the patient's risk;
- evaluating the patient group at risk (track and trace);
- involving the clinicians and formulating the strategy, including a plan for patient information / patient treatment, and a communication plan.

After completion of all actions, the incident should be evaluated to identify possible future improvements in these kinds of procedures or evaluations. Perhaps, new ideas are put forward for next practice incidents.

10.3 Agreements on management

Responsibilities regarding endoscopy are noted in this handbook. Maintenance and repair of endoscopes are handled by the Medical Technology / Clinical Physics; the user does not contact the supplier at this point. In this way, it is possible to properly register all actions that have taken place concerning endoscopes and washer-disinfectors. These actions are registered in logbooks (digital registration system) and reported to the DSRD.

User maintenance to the washer-disinfector and, for example the replacement of filters, detergents, disinfectants, and the self-disinfection, etc. should be performed by the cleaning and disinfection department itself. The activities are to be incorporated in a procedure of the department and reported in a logbook (see example: Appendix 4)

10.4 Assessment of management

With regard to testing procedures, legislation and (national) guidelines are taken into consideration. The head of the department where an endoscopic procedure is performed is responsible for the handling and use of cleaned and disinfected endoscopes and accessories. The operating procedures are periodically tested under the responsibility of the DSRD. For this purpose, the following actions are planned (see Table 3 for an overview):

- The logbooks are assessed once a year;
- The registration of replacement of chemicals is checked every month;
- A consultation with the involved departments about culture results, production numbers, and the expected purchase of materials is held once a year;
- An audit is held at the department once a year
- The procedures are evaluated every 2 years. At the annual audit, it is also tested whether there are possible omissions in the existing procedures and whether additional procedures are necessary.

10.5 Conventions about validation

The washer-disinfectors should meet the Medical Device Directive 93/42/EC and carry the CE mark.
Periodical validation is necessary to guarantee reproducible cleaning and disinfection. The validation is explicitly not meant to prove that the washer-disinfector meets the requirements of the standard and the Medical Device Directive 93/42/EC standards. This has already been established by the manufacturer and the CE mark indicates that the requirements are met. The cleaning and disinfecting power of the machine is largely determined by the rinsing principle, the method of connecting of the endoscope and the parameters of the cleaning and disinfection process in addition to using the chemicals validated by the manufacturer. For the purpose of validation, checks are performed on the process parameters. The effectiveness of the cleaning, disinfection, and rinsing to remove disinfectant from the endoscope are part of the type test and are therefore not again determined during the validation by the hospital.

This document provides assistances to arrange the validation of the washer-disinfector, drying cabinets, and monitoring of flexible endoscopes within the institution.

For the purpose of this handbook, validation is defined as the evaluation of the results of all measurements, tests and inspections performed in a period to obtain assurance that the washer-disinfector complies with the specifications established by the manufacturer.

freely provided the SFERD is listed as the author

Table 3 –*Overview of the management measures*

Measure	At purchase	Monthly	Quarterly	Annually	Biennial	At incidents	After process influencing changes or actions	After maintenance	Optional
Check if new and loan endoscopes can be placed in disinfector and drying cabinet	X								
Microbiological control endoscopes						X			X*
Microbiological control loan endoscopes						X			X*
Inspection endoscopes				X					
Check the cleanliness of the exterior of the endoscopes									X*
Process control test with dummy endoscope			X			X	X	X	
Check the registration on replacement of chemical cans		X							
Microbiological quality of post-disinfection rinse water			X						
Test of channel monitoring using dummy scope			X						
Test of channel connection monitoring			X						
Verification of system specifications of disinfector				X			X*	X*	
Check the channel separators				X					
Check the connectors				X					
Verification of system specifications of drying cabinet				X			X*	X*	
Assessment of logbooks				X			X		
Assessment of traceability registration				X					
Audit execution primary process				X					
Audit of technology and maintenance				X					
Assessment of incident procedure				X					
Assessment of omission protocols				X					
Revision of protocols					X				
Evaluation of management plan					X				

* To the discretion of the DSRD

Based on the specifications, the manufacturer declares that the washer-disinfector meets the essential requirements of the Medical Device Directive 93/42/EC standards. The specifications are the basis for all measurements, tests and inspections.

The results of the measurements and the procedures followed are tested / evaluated according to standards and operating procedures as outlined in this handbook and are recorded together with the underlying information (test reports, measurement data, manufacturer's declarations, etc.) in a report.

The SFERD is of opinion that for the safety of patients the extent of inspection and maintenance of the washer-disinfectors should be carefully recorded. Besides the technical measurements and microbiological checks, the machine safety devices should be checked periodically.
Reliable storage of disinfected flexible endoscopes in drying cabinets is very important to guarantee the usability of the endoscope for a retention period longer than 4 hours. Therefore, drying cabinets should also be validated according to SFERD.

Flexible endoscopes have a complicated construction. Which may cause defects / abnormalities during use. If these defects / disorders are beyond the detection limits of the washer-disinfector, they are not identified and an endoscope can remain contaminated even though it flawlessly completed a disinfection process. This handbook provides assistances for the checking of a number of hygiene related aspects of the endoscopes.

With regard to the question of who executes measurements that are necessary to verify the functioning of the washer-disinfector, the SFERD is of the opinion that the DSRD, in consultation with Medical Technology / Clinical Physics, carries out periodical measurements, tests, and checks and evaluates the results based on the specifications of the manufacturer. The DSRD decides who carries out the measurements, tests and checks. It is obvious to let the measurements, tests and inspections coincide with performing preventive maintenance where possible. This saves time, increasing the availability of the washer-disinfectors. Moreover, it is generally not useful to perform the measurements, tests, and inspections that are carried out during maintenance again by another party. The expert is responsible for making agreements with the relevant parties about the work that is carried out. Obvious parties here are the supplier, the medical technology department, the advisor infection prevention, validation companies, etc.

10.5.1 Normative references

The functional requirements and test methods for washer-disinfectors are described in the following international standards [ref 10.] :

NEN EN ISO 15883-1:2006	Washer-disinfectors - Part 1: General requirements, terms and definitions and tests
NEN EN ISO 15883-4:2008	Washer-disinfectors - Part 4: Requirements and tests for washer-disinfectors employing chemical disinfection for thermolabile endoscopes
NPR CEN ISO/TS 15883-5:2005	Washer-disinfectors - Part 5: Test soils and methods for demonstrating cleaning efficacy

Wherever this document refers to 'the standard' the interaction of the standards referred to above is meant.

10.5.2 Requirements and responsibilities

In this part, the actors, which are relevant in washer-disinfectors validation, are mentioned. These actors have certain responsibilities and must meet certain requirements.

freely provided the SFERD is listed as the author

Contact person
Ensures that the washer-disinfector is used according to work instruction, the endoscopes are prepared according to work instruction, daily and weekly inspections are performed and the logbook is kept. If in doubt about the functioning of the washer-disinfector, the contact person consults the DSRD.

Manufacturer/supplier
The manufacturer / supplier delivers a washer-disinfector that meets the requirements as stated in the purchase-agreement. This means that the washer-disinfector should comply with the Medical Device Directive 93/42/EEC and the standard NEN EN ISO 15883, Parts 1, 4 and 5. The manufacturer specifies clearly, which endoscopes can be processed in washer-disinfector, connection materials are needed for each scope, and which necessary pre-treatments should be performed before the endoscope can be placed into the machine (e.g. brushing of the biopsy channel).
The manufacturer specifies all process parameters and shows how these can be verified. If it is necessary to carry out a temporary adjustment to the machine or the software for the verification of a process parameter, the manufacturer must provide a protocol for this. The manufacturer must also specify the user maintenance.

Owner
The owner provides sufficient resources to enable cleaning and disinfection of flexible endoscopes in a responsible manner. The owner also provides the necessary maintenance of the equipment and staff training.

Technician performing measurements, tests and inspections
Demonstrably competent and specially trained individuals who are familiar with the design, construction, use, and maintenance of washer-disinfector are responsible for performing measurements, tests and checks. The starting points for validation are always specified by the manufacturer. Companies that carry out measurements, tests and checks should operate under a quality assurance system, e.g. ISO 9000. To ensure integrity of the technician, all activities should be performed and reported in accordance with written procedures. The DSRD monitors the execution and reporting of the activities.
Measurements, tests and checks requiring a modification of the washer- (e.g. for placement of measurement sensors in liquid pipelines or modifications to the washer-disinfector programming) should be avoided. If a modification is required to perform a measurement, test or check, this can only be carried out following a protocol provided by the manufacturer.

User
The user should use the washer-disinfector according to the instructions of the manufacturer, as outlined in the work instruction and for the purpose for which the washer-disinfector is designed. The user should be qualified to perform the function and must be instructed in the use of the washer-disinfector. It involves an instruction from the manufacturer / supplier that also focuses on the technical operation of the washer-disinfector with emphasis on the limitations of the washer-disinfector and processes. The user should be able to recognise simple faults and failures and resolve these. If failures cannot be resolved by the user, one needs to inform the Medical Technology / Clinical Physics. Accordingly, the Medical Technology / Clinical Physics registers the notification and subsequent actions in the logbook and informs the DSRD about this. The user and technicians should be able to identify abnormalities in the functioning.

10.6 Validation of the washer-disinfector

The following are STEPs in the validation. The DSRD ensures that all STEPs are performed. The validation of the washer-disinfector should be performed at least once a year. Measurements, tests and checks should be performed after any maintenance or repair, depending on the nature of the changes to or activities on the machine. In any case, a release test should be performed. The manufacturer should indicate whether maintenance or repair has influenced the process, the Medical Technology / Clinical Physics evaluates the arguments of the manufacturer together with the DSRD. In consultation it is decided which release tests are necessary.
Section 10.4 schematically shows the overview of the management measures that make up the validation and which should be performed periodically or if indicated.

10.6.1 Logbook

In the logbook, all data regarding the use of the washer-disinfector should be recorded. Each washer-disinfector has its own logbook. The logbook should be stored close to the washer-disinfector or it consists of an electronic file that can be seen and complemented by the DSRD and the user near the workspace. The following information should be recorded:

- name, location and address of the owner / contact person;
- serial and model number;
- brand and type / version of the washer-disinfector;
- year of manufacture of the washer-disinfector.

The following aspects are recorded in the logbook:

- date of replacement of chemical containers and lot numbers;
- overview of measurements, tests and inspections, with the name of the technician and the results (with reference to protocols and possibly other documents);
- overview of daily, weekly, quarterly and annual inspections with the name of the inspector(s);
- overview of the cleaning activities on the machine with the name of the person performing the activities;
- overview of maintenance with the name of the maintenance technician / service technician and the details of the release tests;
- overview of failures and repairs with the name of the maintenance technician / service technician and the details of the release tests;
- overview of maintenance of water treatment equipment with the name of the maintenance technician / service technician and the details of the release tests;
- details of the replacement of water filters, pre-filters, and bacterial filters.

Note: The replacement of chemical containers can be registered in the logbook, but in practice this is often recorded on a separate list.

freely provided the SFERD is listed as the author

10.6.2 List of endoscopes with compatibility declaration

The washer-disinfector manufacturer should specify for which the endoscopes the washer-disinfector is suitable; NEN EN ISO 15883-4 § 4.1.3. [19] and § 8.a.[20]
By including an endoscope to the list, the manufacturer states that the endoscope will be properly cleaned and disinfected in the process (compatibility statement), provided that the proper connectors are used to connect the endoscope in the washer-disinfector, the prescribed chemicals are used and that the pre-treatment of the endoscope, which is prescribed by the manufacturer of the washer-disinfector, is performed see BS EN ISO 15883-4 § 4.1.4. .[21]

This also means that the institution does not have to test whether the endoscopes can be cleaned and disinfected in the washer-disinfector and disinfected, unless the institution uses endoscopes, of which the manufacturer of the washer-disinfector has not established that the washer-disinfector is suitable.
In that case, the manufacturer of the endoscope can possibly declare that the endoscope can be effectively cleaned in the corresponding washer-disinfector and disinfected. In all other cases, the institution should decide to refrain from buying the endoscope concerned.

Most manufacturers have a list of endoscopes that can be cleaned and disinfected in the washer-disinfector. It is recommended to verify that all endoscopes used in the institution are mentioned on the list before the purchase of the washer-disinfector. The same advice can be given if one intends to purchase a new type of endoscope or if planning to use a loan endoscope. In that case, the connectors should be purchased to properly connect the endoscope in the machine.

Part of the initial validation is to ensure that:

- the endoscopes used in the hospital are on the list of the manufacturer;
- the right connectors are present;
- preparatory activities (such as brushing of the channels), which the manufacturer describes in the work instructions, are included.

Part of the revalidation is to verify in advance whether:

- endoscopes or loan endoscopes are on the list of manufacturer of the washer-disinfector. If not, the manufacturer or the manufacturer of endoscopes should

[19] After the entire process in the WD the endoscope shall be free from vegetative bacteria (but not necessarily spores) and other contamination. The combination of the cleaning process and the disinfection process shall be designed to achieve this condition, recognising the high level of bacterial contamination that may exist. It shall be necessary to take into account other factors such as the design of connectors. The WD manufacturer shall demonstrate this capability during type testing for all the types of endoscope that the WD is designed to process.

[20] In addition to the information specified in ISO 15883-1:2006, Clause 8 the WD manufacturer shall provide the following information: the devices and/or device families for which the WD manufacturer has evidence that they can be processed satisfactorily and any precautions necessary for particular devices or operational conditions

[21] The WD manufacturer's instructions shall recommend that any requirements, e.g. for manual cleaning and or disassembly of the endoscope, prior to processing in the WD, provided by the device manufacturer should be followed.

investigate whether the endoscope can be effectively cleaned and disinfected in the washer-disinfector;
- the right connectors for the new endoscope present;
- the new preparatory activities described are included in the work instructions by the manufacturer.

10.6.3 System specifications

The values of process parameters should be specified for the endoscope washer-disinfector, so that it can be determined by measurements whether the machine still functions within the specifications of the manufacturer. The values of process parameters should be specified by the manufacturer of the washer-disinfector, including the use of detergent and disinfectant and the concentration and temperature in which these agents should be used. All specifications must be provided in measurable quantities, so that it can be verified by measurements.

The parameters of the various process stages are listed in Appendix 6. Depending on the age, the brand and model washer-disinfector, additional process parameters can be relevant or not all of these process parameters are applicable. For all process parameters, the value and allowed tolerances should be specified. If a process parameter is not applicable, this should be substantiated.

10.6.4 Changes made by the manufacturer/supplier

In response to a corrective action of the manufacturer, changes to the washer-disinfector can be made. The DSRD should verify these changes in cooperation with the manufacturer, in which the arguments of the manufacturer should be assessed by DSRD:
- Recorded in the machine logbooks (by the supplier);
- The influence on the cleaning and / or disinfection efficacy for each type of endoscope that can be treated in the washer-disinfector;
- Influences on the reproducibility of the processes;
- Influences on the quality of the post-disinfection rinse water;
- Influences on the effecacy of self-disinfection cycle;

The findings of these evaluations are documented by the DSRD. Where the DSRD determines that the modifications are such that the effecacy and / or reproducibility of the washer-disinfector have been compromised, he may decide to suspend the use of the washer-disinfector. In this case, it is likely that the changes to the washer-disinfector is such that the type tests, as once performed by the manufacturer. The manufacturer should repeat a part of type tests and make the results available to the DSRD.

10.7 Periodical inspections, verification specifications, and other controls

The following inspections, verifications, and controls are typically performed on a predetermined annually schedule. In the event of an incident, it will be necessary to carry out research to determine the cause of the incident. After correcting of the problem, it should be verified whether the washer-disinfector functions within the predetermined specifications again. The nature and extent of the activities that are required will depend on the nature of the incident and the underlying problem. The DSRD should put together and perform a dedicated inspection program, verifications, and controls in these cases.

freely provided the SFERD is listed as the author

10.7.1 Daily inspection washer-disinfector

Before first use on any working day, the washer-disinfector should be visually inspected. The visual inspection consists of:

- enough chemicals in the cans;
- right can at the right place;
- inspection for defects and other deviations that are visible at first sight;
- inspection for leaks;
- inspection for corrosion and / or other deposits that may indicate a leak;
- check whether the notifications on the machine on time of use / maintenance interval have not yet expired.

The manufacturer of the washer-disinfector may recommend additional checks.

10.7.2 Quarterly inspection of the washer-disinfector

PART 1 - Control channel monitoring system

The functioning of the channel monitoring system is checked using a dummy endoscope every three months. The dummy endoscope allows for reduction of flow in each channel. The washer-disinfector should generate an alarm for each blocked channel.

PART 2 - Control channel connection monitoring system

The functioning of the channel monitoring system is checked using a (dummy) endoscope every three months. The channels of the endoscope are connected. One channel is disconnected and the process is started. The disinfector should report an error. The test is repeated for each channel. The disinfector should generate an alarm for each channel that is not connected.

PART 3 - Process control

The verification test is performed using a dummy endoscope (according to NEN EN ISO 15883) and commercially available chemical or biological indicator. Such a test gives a quick insight into the functioning of the washer-disinfector. By comparing the test results over time, an indication on the reproducibility of the washer-disinfector of can be obtained.
After the intermediate rinse between the cleaning phase and disinfection phase is completed, the process is interrupted and the surrogate endoscope is removed from the disinfector, unless the manufacturer of the indicator states that the process can be performed completely (including the disinfection phase).

The result of the test is recorded and compared with the results of previous tests. Attention should be paid to a negative trend. This may be an indication of wear and tear on parts of the disinfector, which could eventually lead to failure of the machine or to an unacceptable decrease in the effectiveness of the cleaning and disinfection process.
The control test is also performed as a release test after installation, maintenance and repair.

PART 4 - Microbiological quality control post-disinfection rinse water

The microbiological quality of rinse water must be determined after installation of the washer-disinfector and / or water treatment installation. It is recommended that this is repeated twice with an interval of one week. Then once more, one month after the final determination. If consistently acceptable results (see acceptance criteria Willes)

are found, it is sufficient to test the microbiological quality of water once every quarter. The protocol for the tests is described in Appendix 7.
There is not only an acceptable result if there are no microorganisms found in the post-disinfection rinse water. The table below shows how the results of microbiological tests should be interpreted and what actions could be necessary.

Table 4 – Acceptance Criteria of Willes in a microbiological test of the post-disinfection rinse water [ref 28.]

Aerobic colonies per 100ml	**Interpretation en possible action**
0	Acceptable.
1-9	Acceptable. Consistently low numbers of bacteria indicates the water treatment is under control.
10-100	Doubtful. Find the cause of the problem, see Appendix 9 and 10
>100	Unacceptable. Discard the washer-disinfector until water quality has improved.

PART 5 – Control of the efficacy of the self-disinfection cycle

The self-disinfection cycle of the washer disinfector is designed to prevent contamination of the washer-disinfectors themselves. The self-disinfection is carried out according to the instructions by the manufacturer. While performing a self-disinfection, parts of the washer-disinfector are disinfected that would not be disinfected during a normal process in most systems. These can be parts of the water supply or water treatment systems (filters).
The microbiological quality of post-disinfection rinse water is actually also an indication of whether the machine is bacteria free. Indeed, if the machine is contaminated with a bio film, organisms can be detected during the check of the post-disinfection rinse water. If bacteria are found during the check of the post-disinfection rinse water, then a water sample should be taken after self-disinfection and tested for the presence of bacteria. For this, the procedure used in Appendix 7 can be used.

Note: Often a thermal self-disinfection is carried out. Perhaps the post-disinfection rinse water is of high temperature, or was of high temperature shortly before sampling. Therefore, it is likely that "thermally disinfected" water will not be contaminated. A chemical self-disinfection is performed with an higher concentration of chemicals in some systems, which may increase the concentration of residues in the rinse water. If the sample still contains disinfectant, a potential risk of contamination might not be discovered. To identify a contaminated washer-disinfector or water inlet system it is necessary to run a normal process after performing a self-disinfection procedure and then determine whether the post-disinfection rinse water of this normal process is free of bacteria.

10.7.3 Annual inspection of the washer-disinfector

All system specifications should be verified at least once a year (see 10.6.1). Where necessary, adjustments are made, e.g. by adjusting the sensors. The DSRD checks whether the verification of the system parameters is performed according to a protocol dedicated for the washer-disinfector.
Before verification starts, the washer-disinfector logbook is reviewed to determine whether there are details that should be taken into account during the verification.
Verification of all system specifications can be performed by any qualified party (supplier, validation agent, Medical Technology/ Clinical Physics), but can be

freely provided the SFERD is listed as the author

combined with the maintenance for reasons of efficiency, as many parameters should be checked during maintenance anyhow.
Clear agreements should be made with the party that performs the verification procedures on what verification will be done, by what method and with what accuracy. The DSRD finds another party for inspections not covered by the maintenance company. The DSRD checks whether the party concerned is competent and has adjusted its procedures to the washer-disinfector manufacturer.

WARNING: It is strongly discouraged to make (temporary) modifications to the washer-disinfector for the performance of the verification measurements or controls. E.g. disconnecting tubes in the washer-disinfector in order to place sensors, disconnecting sensors to test warning systems, or changing the process parameters. There is a risk that the modifications are not properly restored after performing the measurements. The machine will no longer function as intended by the manufacturer and the processes may not be performed effectively. In this way, the verification measurements and controls become a danger to the patient! Adjustments in the technique of the washer-disinfector are to be done by the supplier, if it is only to guarantee the validity of the CE-marking and the related product liability of the manufacturer. In case the manufacturer indicates that a temporary modification is necessary to perform certain measurements, he must provide a procedure for this.

The results of measurements, tests and inspections are documented. If corrections are made in sensors and measurement systems, the condition before the correction is also reported. E.g. if a temperature sensor shows a value that is too low, the sensor should be adjusted so that it shows the correct value again. Any deviation should be recorded in the report as well. The DSRD should verify whether this deviation adversely affected the effectiveness of the process and whether the patient safety has been at stake due to this deviation. In severe cases, a look back of the patients should be considered.

10.8 Other controls washer-disinfector

Verification of the efficacy of the disinfection process

If in doubt about the effectiveness of the disinfection process, it must be verified whether the disinfectant prescribed by the manufacturer is used. Also, the process parameters that can influence the effectiveness of the disinfection process should be verified. Additionally, the concentration of the active ingredient in the disinfectant can be determined. Perhaps the concentration of the active ingredient in the disinfectant is not consistent with the concentration indicated on label.

10.9 Release washer-disinfector for use

Approval / release is done by the Medical Technology / Clinical Physics, in agreement with the DSRD, if all conditions of chapter 10.6-10.8 are met.
Taking out of service occurs when one or more conditions are not met. The DSRD weighs the severity of the deviation and decides whether the washer-disinfector should be taken out of service, in consultation with Medical Technology / Clinical Physics.

Indication approval

If it turns out that the washer-disinfector is safe to use after validation, a clear mark should be placed on the washer-disinfector by means of an approval sticker issued by

the Medical Technology / Clinical Physics. In addition, the validity (best before date) should be indicated on the sticker.

Indication out of service

If the validation indicates that the washer-disinfector is not safe to be used, a clear mark should be placed on the washer-disinfector with the out of service sticker. This mark must always be red and provided with a date. Reason for taking out of service can be that the washer-disinfector is damaged so that safe operation is not possible, maintenance / repair is no longer possible or if this is a logical conclusion based on the validation results.
This information should be included in the logbook, including the conclusion, "disqualified". A washer-disinfector that does not meet the requirements should be taken out of service in such a way that it actually cannot be used.

10.10 Validation drying/storage cabinets

The validation of drying cabinets is derived from the N784 CEN/TC102 NWIP STORAGE CABINETS heat-sensitive endoscopes (version January 2008) and focuses on the Dutch market. This EU standard for drying cabinets is merely a first draft. The final version is possibly some years away. Hereby the SFERD tries to give direction to the validation procedure drying cabinets.
Because of the wide variety of drying cabinets, existing cabinets will not in part or not at all meet these requirements. When buying or replacing drying cabinets, it is advisable to include the validation possibilities in the set of requirements.

10.10.1 Difference between drying- and storage cabinet

A drying cabinet is a cabinet in which a disinfected flexible endoscope can be hung wet and where the channels of the endoscope can be connected to pass heated and / or dried HEPA filtered air through the channels. A drying cabinet dries the entire endoscope; the channels and the exterior. The drying cabinet can be connected to a tracking / recording system by which it can be easily determined for how long each endoscope is placed in the cabinet.
A storage cabinet is an enclosed cabinet with overpressure at room temperature, in which a dried flexible scope is stored. The difference between a drying cabinet and a storage cabinet is that the drying cabinet dries the channels of the endoscope with dry HEPA-filtered air. Therefore, endoscopes without channels do not require a drying cabinet.

10.10.2 Documentation

A (digital) logbook has to be created directly at purchase of a drying/storage cabinet. This logbook should contain the following information and documents:

- date of placement on site
- product specification according to the Schedule of Requirements
- process specification according to manufacturer's specifications
- safety features
- type test declaration
- wiring diagrams of piping, automation etc.
- technical manual
- declaration of conformity for endoscopes that can be dried in the cabinet
- maintenance protocol
- connection instructions for each type of endoscope
- user manual

freely provided the SFERD is listed as the author

- cleaning protocol
- loading protocol
- connection protocol
- discharge protocol

In addition, the following environmental factors should be recorded:

- spatial conditions:
  - temperature, humidity and ventilation
- electrical specifications:
  - power and voltage
- compressed air specifications:
  - capacity, static and dynamic pressures
  - quality (particles, moisture, absence of oil)

10.10.3 Validation points drying/storage cabinet

- Is all documentation present in the logbook?
- Has it been determined who releases, periodical maintains, and repairs the drying/storage cabinet after purchase?
- Is the connection tubing still intact?
- Are all fittings still intact?
- Are the channels actually purged?
- Are all suspension clips still intact?
- Is maintenance carried out according to protocols?
- Is the drying/storage cabinet cleaned according to protocols?
- Does the drying/storage cabinet function according to the specification, are the (critical) [22] parameters set by the manufacturer within tolerances?
- Does the drying cabinet provide a signal for a faulty drying process?
- Does the drying cabinet provide a signal when the maximum storage time has expired?
- Does the drying cabinet provide a signal if the door is not closed properly?
- Does the drying cabinet provide a signal if the power supply fails?
- Have the environmental conditions changed?

Automation

It is desirable that the drying cabinets can be connected to a trace system of flexible endoscopes as is used in the hospital.

10.11 Control Flexible Endoscopes

It is possible that an endoscope underwent a validated cleaning and disinfection process, but due to damage / malfunction of the endoscope (e.g. a tear in the biopsy channel or the cardan rubber) disinfection has been insufficient so it can still be contaminated. These damages / defects are not always detected by a leak test. To ensure an effective cleaning and disinfection, it is also important that the connectors, which connect the endoscope to the washer-disinfector or the drying cabinet, are connected and that the channel separators are in order. The SFERD suggests that the scopes, connectors, and channel separators are inspected annually.

Microbiological testing of flexible endoscopes, as described in this section, is not intended to verify proper operation of the washer-disinfector. It is therefore of no use to sample endoscopes periodically. The SFERD decided to include the monitoring

[22] Where applicable, such as temperature, relative humidity, flow through channels, flow through cabinet, HEPA filter condition.

techniques in the handbook because situations can occur, in which it is useful to check whether the source of infection can be the endoscopes. Endoscopes are only microbiologically controlled following a specific defect of the scope, washer-disinfector, water treatment, or drying cabinet, and a suspected incident of endoscopy-related infections.
The procedures described are general, i.e. for each (type of) endoscope it should be determined which channels and other risks items should be checked.

10.11.1 Annual inspections of the endoscopes and accessories

The endoscope should be inspected annually. This can be performed by the instrumentation technician of the institute, supplier of the endoscopes, or by a specialized maintenance company. The inspections should be performed on the following hygiene related issues:

- faults and defects that are visible at first sight;
- corrosion or other deposit;
- cleanliness of the exterior of the endoscope, including the operation panel and the connection to the light source;
- wear and tear of the coatings, readability of the length markings on the endoscope;
- state of the connection to the light source, compressed air, and water bottle;
- readability of the type designation and serial number or other unique identification number;
- functioning of the RFID chip;
- correlation RFID chip data and the data of the endoscope;
- leaks (manual leak test control that involves movement of the cardan).

10.11.2 Checking connectors

The connection between machine and endoscope should not influence the operation of the machine as a result of leaks, flow restrictions, or other limitations.
The check of connectors includes inspection of:

- state of the O-rings and interface with the endoscope
- damage to the connector and tubes attached to the connector

10.11.3 Checking channel separators

The channel separators should not influence the operation of the machine as a result of leaks, flow restrictions, or other limitations.
The check of channel seperators includes inspection of:

- the mechanical action of movable parts; do the parts slide smoothly;
- attachment of solid pars; are the parts that need to jammed actually jammed;
- completeness of the channel separator; are parts missing;
- state of O-rings and interface with the endoscope;
- damages; scratches, bending of parts.

10.11.4 Optional control of the endoscopes

POSSIBILITY 1 - Microbiological Control Endoscope Channels

The channels of the endoscope can be microbiologically checked by rinsing the channels with sterile saline, the method is described in Appendix 7.

Elaboration method laboratory
See Appendix 7

freely provided the SFERD is listed as the author

Interpretation positive culture
See flowchart and assessment list Appendix 8 and 10

POSSIBILITY 2 – Checking the cleanliness of the endoscope

Check the cleanliness of the exterior of the endoscope, including the operation panel and the connection to the light source. The inspection is conducted visually. Contamination residues can be made clearly visible by wiping the surface with a damp swab. By the use of ninhydrin (see Appendix 11), protein residues on the swab are stained and by the use of TMB (see Appendix 12), hemoglobin is made visible.

Note. The ATP measurement is used in the food industry to obtain an overall impression of the bacterial contamination on surfaces in a quick manner. The ATP measurement is not sufficiently developed as a control method for endoscopes. Research information and acceptance criteria are missing in order to apply this method effectively.

Appendix 1- Bibliography

[1.] State Supervision Public Health, Letter to Hospital Managements, Hygienists / departments hospital hygiene, pulmonologists, medical microbiologists and hospital pharmacists about brochoscopes, GHI/JK/DV/93557; Rijswijk, February 1993

[2.] State Supervision Public Health, Letter to Pulmonologists, directors of hospitals, medical microbiologists, hospital hygienist, Hospital Pharmacists and Experts sterilised medical accessories, GHI/INFZ/93647; Rijswijk, November 1993

[3.] State Supervision Public Health, Health Care Inspectorate report "Scope Disinfection in Dutch hospitals", The Hague, April 2000

[4.] State Supervision Public Health, Health Care Inspectorate report 'Follow-up research scope Disinfection ", The Hague, June 2004

[5.] Workgroup Infection Prevention, directive "Cleaning and disinfection of endoscopes", Leiden, April 2009 (www.wip.nl)

[6.] State Supervision Public Health, Letter to Hospital managements or Board of Directors of hospitals, medical microbiologists and hospital hygienist, 1997-1905 IGZ, Rijswijk, March 1997

[7.] Bronchoscopy related Infections and Pseudoinfections in New York, 1996 and 1998, MMWR Weekly, July 9, 1999 / 48(26); 557-560

[8.] Agerton et al., Transmission of a highly Drug Resistant Strain (Strain W1) of Mycobacterium tuberculosis, JAMA, October 1, 1997 – vol 278, No. 13

[9.] Michele et al., Transmission of Mycobacterium tuberculosis by a fiberoptic brochoscope, JAMA, October 1, 1997 – vol 278, No. 13

[10.] NEN-EN-ISO 15883, Disinfecting wasing machines.

[11.] Workgroup Infection Prevention, directive "Storage and transportation of used instruments for sterilisation", Leiden, December 2007 (www.wip.nl)

[12.] Construction standards, central sterilisation department, Board for Healthcare Institutions, November 18, 2002

[13.] Construction atandards consultation department, outpatient therapy and general examination organfunction; Board for Healthcare Institutions, 2004

[14.] NEN 1010 Safety requirements for low voltage installations

[15.] NEN-EN-7396-1 Medical gas pipeline systems - Part 1: Pipeline systems for medical gases under pressure and vacuum

[16.] Safety program prevent damage, work safely in Dutch hospitals, Health, Welfare and Sport (VWS), June 2007

[17.] ESGE/ESGENA guideline for process validation and routine testing for reprocessing endoscopes in washer-disinfectors. Endoscopy 2007; 39: 85-94

[18.] ESGE/ESGENA guideline for quality assurance in reprocessing: Microbiological surveillance testing in endoscopy. Endoscopy 2007; 39: 175-181

[19.] Standards for Endoscopic Facilities and Services, 3th Edition 2006. Gastroenterological Society of Australia/Gastroenterological Nurses Society of Australia

[20.] ESGE Guideline for Quality Control of Endoscope Service and Repair (2004). Endoscopy 2004;36(10):921-3

[21.] ESGE/ESGENA Technical Note on Cleaning and Disinfection (2003) Endoscopy 2003; 35: 869 – 877

[22.] ESGE-ESGENA guideline: Cleaning and disinfection in gastrointestinal endoscopy, update 2008;Endoscopy 2008; 40: 939-957

[23.] "Clean" is not clean enough, microbiological safety around endoscopy can be improved J. Kovaleva et al, Medisch Contact 64 No. 23, June 4, 2009: 1041-1043.

[24.] Letter Report 360050013/2008 quality of cleaning and disinfection of flexible endoscopes Reprise Adrie de Bruijn, Arjan van Drongelen RIVM, July 2008

[25.] State Supervision Public Health, Health Care Inspectorate report 'Risks of medical technology underestimated ", The Hague, October 2008

[26.] CEN/TC102 N784 NWIP STORAGE CABINETS-heat-sensitive endoscopes, Version 1, september 2004

[27.] Directive 93/42/EEC European Council of 14 June 1993 concerning medical accessories

[28.] Willis, C., Bacteria-free endoscopy rinse water - A realistic aim? Epidemiology and Infection, 2005. 134(2): p. 279-284

[29.] Performance Indicators Quality Assurance Medical Systems, Dutch Society of Clinical Physics, May 2007

[30.] Guideline Responsibility medical specialist in maintenance and management of medical equipment, Order of Medical Specialists, October 17, 2008

[31.] Pidduck D. Cross infection and the laryngoscope. Br. J. Perioper. Nurs. 2002 May; 12(5):170-5.

[32.] Lo Passo C, Pernice I, et al. Transmission of Trichosporon asahii oesophagitis by a contaminated endoscope. Mycoses. 2001; 44(1-2):13-21

[33.] Wenzel RP, Edmond MB. Tuberculosis infection after bronchoscopy. JAMA 1997 Oct 1; 278(13):1111

[34.] Agerton T, Valway S, et al. Transmission of a highly drug-resistant strain (strain W1) of Mycobacterium tuberculosis. Community outbreak and nosocomial transmission via a contaminated bronchoscope. JAMA 1997 Oct 1; 278(13):1073-7

[35.] Chauffour X, Deva AK, et al. Evaluation of disinfection and sterilization of reusable angioscopes with the duck hepatitis B model. J.Vasc Surg. 1999 Aug ; 30(2) :277-82

[36.] Cox R, deBorja K, et al. A pseudo-outbreak of Mycobacterium chelonae infections related to bronchoscopy. Inf. Control Hosp. Epid. 1997 Feb; 18(2):136-7

[37.] Kressel AB, Kidd F. Pseudo-outbreak of Mycobacterium chelonae and Methylobacterium mesophilicum caused by contamination of an automated endoscopy washer. Inf. Control Hosp. Epid. 2001 Jul; 22(7):414-8

[38.] Silva CV, Magalhaes VD, et al. Pseudo-outbreak of Pseudomonas aeruginosa and Serratia marcescens related to bronchoscopes. Inf. Control Hosp. Epid. 2003 Mar; 24(3):195-7

[39.] EN-ISO 17664 (2004) Sterilization of medical devices - Information to be provided by the manufacturer for the processing of resterilizable medical devices

[40.] Quality Act Healthcare Institutions, 2010

[41.] Act on professions in individual healthcare, 1993

[42.] A. J. Buss, M. H. Been et al. Endoscope disinfection and its pitfalls ± requirement for retrograde surveillance cultures. Endoscopy 2008; 40: 327-332

[43.] Decree sterilised medical accessories in hospitals, Article 7 paragraph 3 (1983)

[44.] Decree sterilisation companies medical accessories, Article 6 paragraph 3 (1989)

Appendix 2 – Form for conveyance of a damaged or leaking endoscope

Checklist for user

The exterior of the endoscope is wiped off with alcohol

The channels are dried
Note: If an endoscope is send in "wet", this can lead to major damage to the endoscope.

Label indicating "disinfected yes/no" attached to the endoscope
Failure reported to department of Medical Technology / Clinical Physics

To be completed by the user

Inventory code of the endoscope

Description of the problem

The endoscope is …. by the user:
wiped off with alcohol
manually cleaned
mechanically disinfected

Inventory code of the washer-disinfector

Checklist for the technician

- Handle the endoscope while wearing gloves, possibly use safety goggles and a mouth mask.
- Wrap the endoscope in foil and take it to the transportation case.
- Indicate the state of manual of manual pre-cleaning and / or disinfection on the case and inside the case.

freely provided the SFERD is listed as the author

Appendix 3 – Decontamination form

Place: Date:

The undersigned declare that the instrumentation (order number)**……**

……

……

……..

is **DECONTAMINATED** [1)] .

Note
It is not allowed to clinically use instrumentation that is used **for animals or for obduction**.
These instruments may no longer be offered for human use again.

Name supplier: Name institution:

_____ _____

Signed for this supplier :

_____

Signed for Department of cleaning and disinfection:

_____

1) Describe method of decontamination

Appendix 4 – Routine application of daily maintenance of the washer-disinfector

Form start-up and control washer-disinfector
Month …… Year 20……
Washer-disinfector nr. ……..

Date	Every 1st workday of the week Self-disinfection	Daily Check detergent and disinfectant	Daily Check O-rings	Daily Check tubes	Daily s Clean operating panel + handles	Replace detergent	2x signature	Replace disinfectant	2x signature	Weekly Softening	Weekly Clean drain + polish machines	Malfunctions

Appendix 5 – Release form for flexible endoscopy after maintenance

□ Release Washer-disinfector specification: ……..

□ Technical validation correct dated ……. by: ……

□ Microbiological validation correct dated……. by: ……

□ Release Flexible Endoscope specification: ……..

□ Technical validation correct dated …… by: ……

□ Microbiological validation correct dated …… by: ……

□ Release Drying Cabinet specification: ……..

□ Technical validation correct dated…… by …….

Abovementioned instrument is hereby released for responsible use up to one year after date. The release is no longer valid if the instrument / equipment is repaired / subjected to radical maintenance is in this year.

Date release: ……

Signature Expert on Endoscope Cleaning & Disinfection (DSRD):

……

This release statement is filed by the DSRD and a copy of this statement will be sent to the head Medical Technology / Clinical Physics and the head of the endoscopy department.

Appendix 6 – System specifications of the washer-disinfector

Parameter	*Specified values and tolerances*	*Measured values*	*Correct*
I Pre-rinsing			
The number of rinsing steps			
The amount of water that is taken			
The quality of the water that is taken (see VI)			
The temperature of the incoming water			
The time the machine needs for the water to heat up to the rinse temperature			
The temperature of the water during the rinsing phase			
The time of the actual rinsing phase, (which is the time after the rinse temperature is reached)			
The pressure of the pump(s) at a given flow value and / or,			
The flow generated by the pump(s) at a given pressure			
Rotation speed wash arms			
II Cleaning			
The amount of water that is taken			
The quality of the water that is taken (see VI)			
Dosage of detergent			
The time the machine needs to heat up the detergent solution to the washing temperature			
The temperature of the detergent solution during the wash phase			
The temperature of the walls of the washing room during the wash phase			
The time of the actual rinsing phase, (which is the time after the rinse temperature is reached)			
The pressure of the pump(s) at a given flow value and / or,			
The flow generated by the pump(s) at a given pressure			
Rotation speed wash arms			
III Rinsing between cleaning and disinfection			
The number of rinsing steps			
The amount of water that is taken			
The quality of the water that is taken (see VI)			
The temperature of the incoming water			
The time the machine needs for the water to heat up to the rinse temperature			
The temperature of the water during the rinsing phase			
The time of the actual rinsing phase, (which is the time			

freely provided the SFERD is listed as the author

Parameter	*Specified values and tolerances*	*Measured values*	*Correct*
after the rinse temperature is reached)			
The pressure of the pump(s) at a given flow value and / or,			
The flow generated by the pump(s) at a given pressure			
Rotation speed wash arms			
IV Disinfection			
The number of rinsing steps			
The amount of water that is taken			
The quality of the water that is taken (see VI)			
The temperature of the incoming water			
The time the machine needs to heat up the disinfectant solution to the disinfection temperature			
The temperature of the disinfectant solution during the disinfection phase			
The temperature of the walls of the washing room during the disinfection phase			
The time of the actual disinfection phase, (which is the time after the disinfection temperature is reached)			
The pressure of the pump(s) at a given flow value and / or,			
The flow generated by the pump(s) at a given pressure			
Rotation speed wash arms			
V Final rinse			
The number of rinsing steps			
The amount of water that is taken			
The quality of the water that is taken (see VI)			
The temperature of the incoming water			
The time the machine needs for the water to heat up to the rinse temperature			
The temperature of the water during the rinsing phase			
The time of the actual rinsing phase, (which is the time after the rinse temperature is reached)			
The pressure of the pump(s) at a given flow value and / or,			
The flow generated by the pump(s) at a given pressure			
Rotation speed wash arms			
VI Quality of the water used in the disinfector			
Temperature			
Hardness			
Content of other minerals			
Amount and type of micro organisms			
Details on integrated softeners, ion exchangers, RO			

Parameter	*Specified values and tolerances*	*Measured values*	*Correct*
membranes, etc.			
Maintenance thereof			
Disinfection thereof			
Integrated filters			
Maintenance thereof			
Disinfection thereof			
Note: The specifications of the manufacturer for of the water quality can differ for each process stage.			
VII Self-disinfection			
The amount of water that is taken			
The quality of the water that is taken (see VI)			
The temperature of the incoming water			
If applicable, the amount of disinfectant that is dosed			
The time the machine needs to heat up the disinfectant solution to the disinfection temperature			
The temperature of the disinfectant solution during the disinfection phase			
The temperature of the walls of the washing room during the disinfection phase			
The duration of the actual disinfection phase			
The pressure of the pump(s) at a given flow value and / or,			
The flow generated by the pump(s) at a given pressure			
Rotation speed wash arms			
VIII Moisture removal from the channels at the end of the process			
Quality of the air that is used for purging of the channels			
Intended air pressure			
Intended temperature of the air			
Setting of the pressure relief (to prevent damage to the endoscope)			
Duration of purging			
IX Leak detection test			
Note: The parameters for the leak detection test have no direct influence on the result of the cleaning and disinfection, but the leak detection is an important PART of the process that can be simply involved in the validation			
Intended pressure			
Setting of the pressure relief (to prevent damage to the endoscope)			
Setting of the alarm threshold for the vacuum or pressure drop during the test			

freely provided the SFERD is listed as the author

Parameter	*Specified values and tolerances*	*Measured values*	*Correct*
Maximum temperature change of the endoscope during the test			
X Monitoring, recording and control, intended threshold values, including the permitted tolerances			
Threshold limits of flow reduction or pressure increase (or change of another variable) during congestion control, before an alarm is given.			
Threshold limits of the flow increase or pressure decrease (or change of another variable) during control of unconnected channels,			
Threshold limits of the maximum pressure that may be delivered by a connector / may occur in the channels of the endoscope, before an alarm is given.			
Threshold limits of the min / max temperature, before an alarm is given.			
Threshold limits for min / max dose of detergent and disinfectant, before an alarm is given.			
Maximum operational life and maximum number of cycles for reuse of disinfectant, before an alarm is given.			
Threshold limits of the measured parameters, or systems that check the nature of the detergent and / or disinfectant (viscosity, refractive index, colour) to recognise exchange of chemicals, before an alarm is given.			
The parameters recorded during the process.			
The accuracy of each measurement system that registers a parameter.			
The specifications of machine specific system securities.			

Appendix 7 – Determination of microbiological quality

Post-disinfection rinse water

MICROBIOLOGICAL CONTROL LATS RINSE WATER WASHER-DISINFECTOR	
Test on aerobic mesofilic microorganismen (aerobic mesophilic bacteria)	
Frequency	Quarterly, at validation, and after processes influencing repair
Collection quantity	100cc
Method	0,22 – 0,45 µm filter
Culture medium	Filter on R_2A
Culture temperature	28-32 °C
Duration incubation	5 days
Standard	<10 cfu/100ml. See review list of possible causes for each pathogen
Test on Mycobacteria (environmental Mycobacteria)	
Frequency	If indicated, e.g. proven inadequate cleaning phase or report of increased number of patients with (atypical) mycobacteria.
Collection quantity	Using conventional culture method from own laboratory
Method	
Culture medium	
Culture temperature	
Duration incubation	
Standard	No Mycobacteria
Test on Legionella	
Frequency	The water supply network regularly cultures according to Legionella management. Endoscopy management does not recommend additional cultures.
Collection quantity	
Method	
Culture medium	
Culture temperature	
Duration incubation	
Standard	<100 cfu / L Legionella

The water treatment system should be maintained and disinfected according to the directives of the manufacturer. In order to perform microbiological determinations, check whether this has been done.

- Perform a normal cycle, particularly if the determination is performed after self-disinfection of the disinfector.
- Take a sample of the post-disinfection rinse water of the process using aseptic technique. Make use of the sampling protocol provided by the manufacturer of the disinfector[23]. Collect per test at least 100 ml of water in a sterile container.
- If the water for the post-disinfection rinse is disinfected by adding a small amount of disinfectant in the washer-disinfector, a neutralizing agent must immediately be added to the sample. The manufacturer of the washer-disinfector can identify the appropriate neutralizing agents.

[23] NEN EN ISO15883-4:2008 §8 Information to be supplied by the manufacturer

freely provided the SFERD is listed as the author

The microbiological investigation takes place as follows:

- Filter the rinse water over a 0.22-0.45 µm membrane and subsequently lay the membrane on an R_2A-agar plate[24].
  Warning: the technique of "spread plating of the water sample" is not suited for the detection of very small numbers of bacteria.
- Incubate at 28-32°C for at least 5 days
- Assess growth and possibly determine germ counts.
- Growth should consist of less than 10 cfu/100 mL (see Appendix 9).
- In case of growth (> 10 cfu/100 mL), carry out determination.
- If the washer disinfector is used for cleaning and disinfection of bronchoscopes, the test (if indicated) should be repeated *on Mycobacteria and / or Legionellae* in the event of growth. This requires specific culture media and incubation times. The water should be free of these microorganisms.

Standard:

- See Willes acceptance criteria, section 10.7.2
- See Appendix 9 flow chart post-disinfection rinse water culture
- See Appendix 10 positive cultures assessment list

Check endoscope channel

Sample collection supplies:

	Note
gloves	
sterile Luer syringes 25 ml	depends on number of available channels
possibly sterile aspirating needle	
bottle with 100 ml of sterile saline	20 ml per channel (flush forceps elevator channel possibly in 2x10ml portions)
sterile tubes	Number depends on available channels
sterile containers	Number depends on available channels
Sterile brush/ or sponge	To brush off bio film
Sterile channel separator	To make sure that the actually intended channel is sampled
Laboratory form for bacteriological analysis	

[24] NEN EN ISO 15883-1:2006 §6.4.2.4

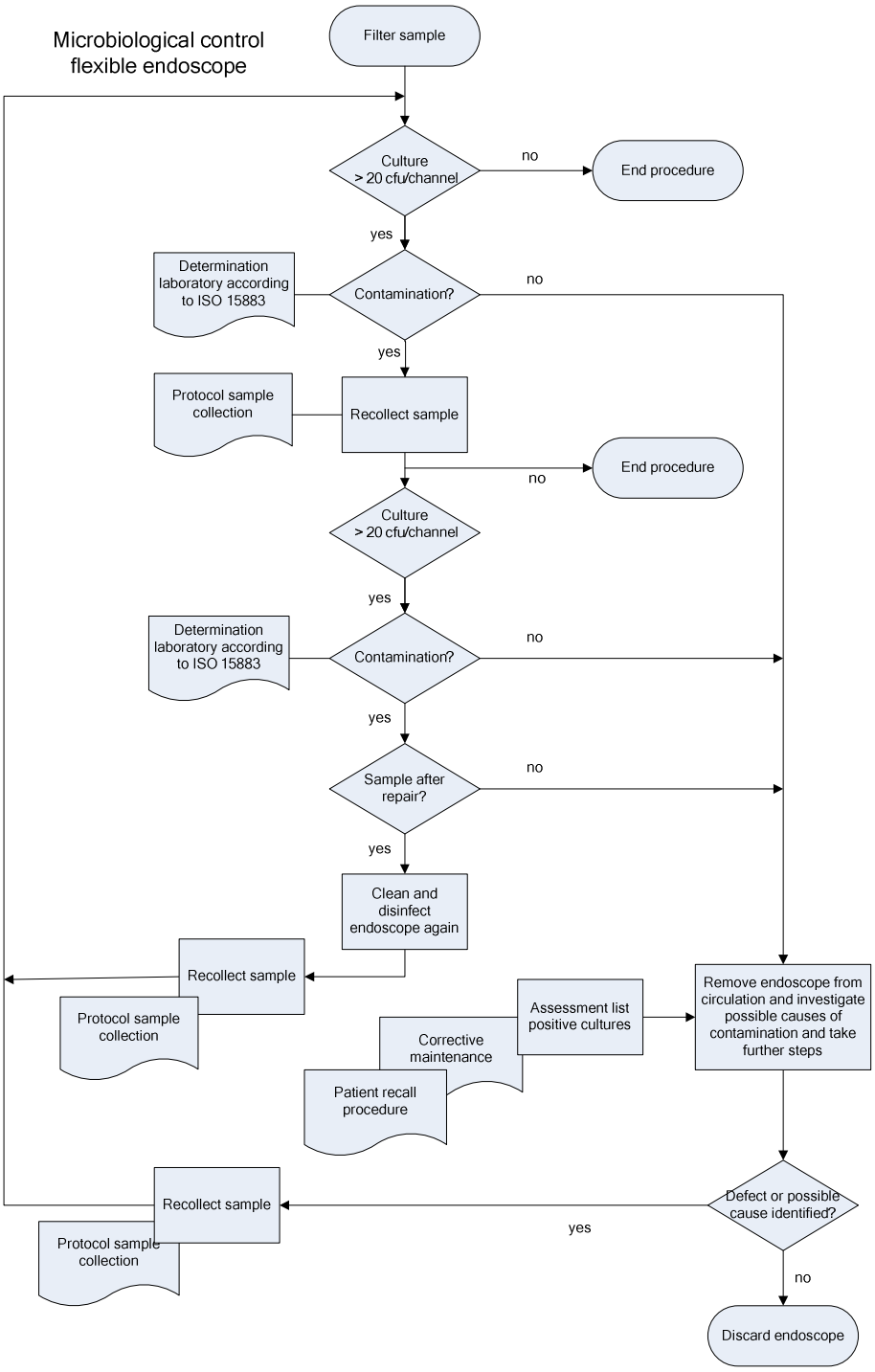
Sample collection[25]

- Two people are needed for the aseptic removal of samples of a flexible endoscope.
- Both persons disinfect their hands before culture collection.
- Both persons wear gloves.
- Disconnect the various connections of the endoscope after the disinfection (see instructions of manufacturer).
- Leave the endoscope in the washer-disinfector tank if possible or place the endoscope on a sterile surface.
- Place the channel separator.
- Ensure that all available channels are sampled: suction / biopsy channel, water / air channel, forceps elevator channel (ERCP scope), jet channel etc.
- If necessary, use a sterile tube to connect a syringe to a channel.
- Rinse suction channel with 20 ml sterile saline solution, while the biopsy input is temporarily kept closed and the rinsing liquid rinse fluid on the tip is collected in a sterile container. Move the syringe plunger powerfully up and down three times during rinsing. Blow air through channels with syringe until all rinsing liquid rinse fluid is collected in a container (keep biopsy input closed).
- Rinse biopsy channel through the biopsy input with 20 ml sterile saline while the suction channel is kept closed and the rinsing liquid on the tip is collected in a sterile container. Move the syringe plunger powerfully up and down three times during rinsing. Blow air through channels with syringe until all rinsing liquid is collected in a container.
- Brush the suction channel and biopsy channel with a properly fitting sterile brush. Beat the brush in a container with rinsing liquid or cut the single-use brush off. Mark the sample with origin of the sample and date.
- Rinse water-air channel with 20 ml sterile saline and collect it on the tip in a sterile container (indicate sample origin on container).
- Rinse any other channels with 20 ml sterile saline.
- Rinse the forceps elevator channel with 20 ml of sterile saline, optionally in portions of 2x10ml.
- Note the sample origin, date and time and reason for culture collection (periodic monitoring / after repair / after purchase / repeat culture after positive results) on the laboratory form.
- Transport samples as soon as possible to the laboratory for examination. In case of longer transport times (> 4 hours) measures should be taken according to agreements with the laboratory concerned.

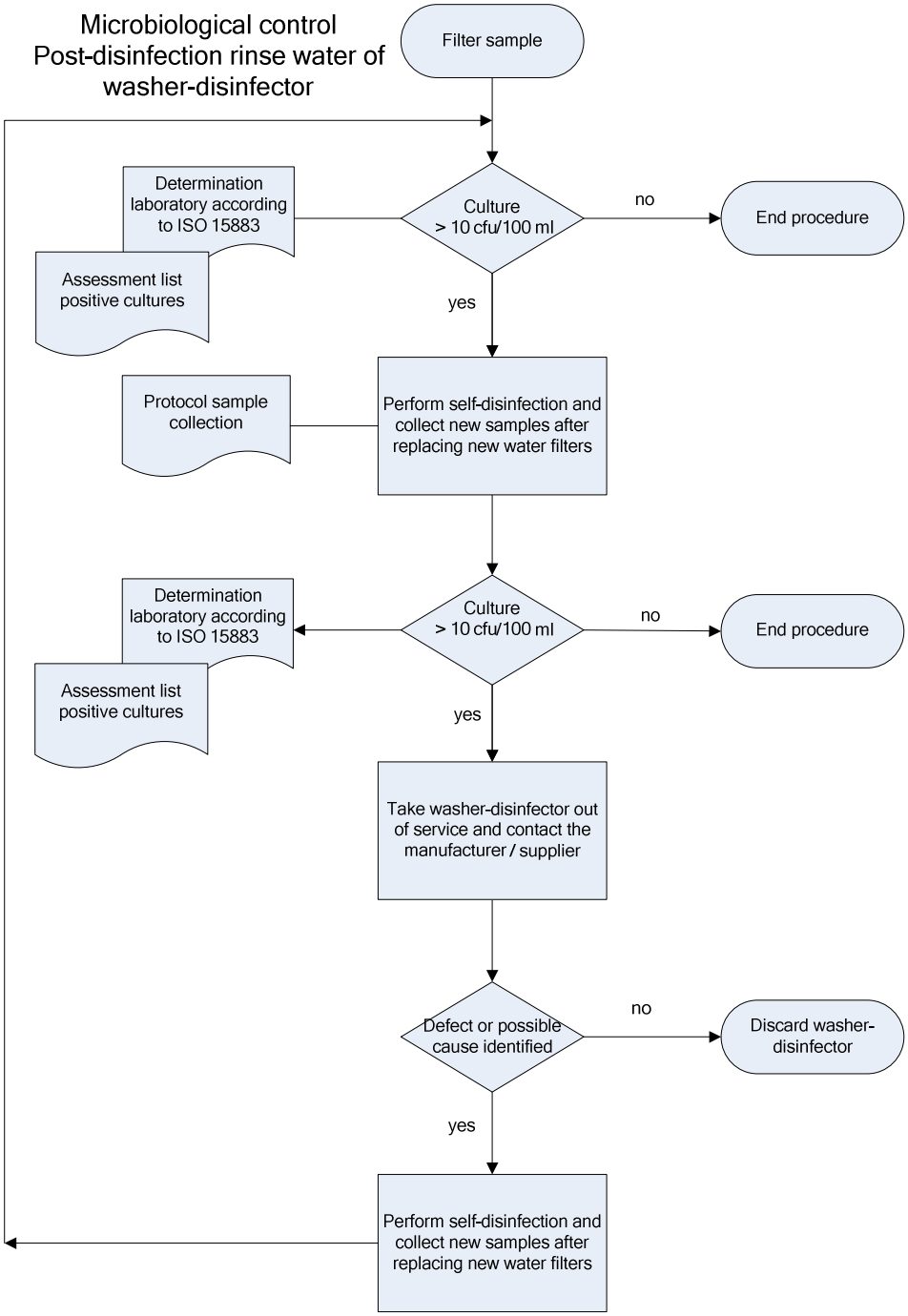
[25] A retrograde culture method can also be used for microbiological testing of endoscopes, see [ref 42]

freely provided the SFERD is listed as the author

Appendix 8 – Flow chart for microbiology tests on flexible endoscopes



Appendix 9 - Flow chart for microbiology tests on the post-disinfection rinse water



Appendix 10 - Estimation sheet on microbiology in endoscopes and/or washer disinfectors

MICRO-ORGANISMS		POSSIBLE CAUSES	ACTION
Escherichia coli, other Enterobacteriaceae Enterococcus	A	– no adequate cleaning and / or disinfection procedure (especially manual cleaning)	A – check the entire process cycle with special focus on the manual cleaning – culture the positive endoscope again
	B	– mechanical or electronic malfunction of the disinfection machine or defective endoscope	B – perform a complete maintenance of the machine – perform a microbiological control of the post-disinfection rinse water – culture the positive endoscope again
Pseudomonas and other non-fermenting Gram-negative rods	A	– insufficient final rinse – contamination of the rinse water – contamination of disinfection machine due to mechanical or electronic malfunction. – contamination of the filters – defective endoscope	A - Check the water supply and the procedures: – manual and / or machine rinsing – perform a complete maintenance of the machine and filters – culture positive endoscope again – culture the rinse water
	B	– insufficient drying of the endoscope during storage – defective endoscope	B – check the function of the drying cabinet – culture the positive endoscope again
(possible contaminants) Staphylococcus aureus, Coagulase neg Staphylococcus Micrococcus Bacillus species	A	– recontamination of the endoscope due to: • inadequate storage and transport • inadequate hand hygiene	A – check the procedure for storage and transport – culture the positive endoscope again
	B	– contamination of material due to incorrect sampling technique or errors in development of the cultures	B – check the procedure for sample collection and elaboration – culture the positive endoscope again
	C	– inefficient drying process	C – check the drying procedure for storage and the ventilation of the storage – culture the positive endoscope again
Atypical Mycobacteria Legionella (Specific cultivation method)	A	– contamination of disinfection machine – contamination of water supply system	A – check the water supply system and procedures: • manual and / or machine rinsing • perform a complete maintenance of machines and water filters – culture the positive endoscope again – culture the rinse water

Appendix 11 - Ninhydrine swab test

Note: This is the basic procedure, the fluid quantity and the incubation period used for the specific swabs, incubator, and incubation temperature should be qualified. [26]

Materials

- Swabs, simple cotton swabs (plastic)
- Incubator set at 220 °C
- Optional needles (0.9 x 70) to avoid bending of the swabs during the incubation
- Water for injection
- Ninhydrin (Order No. N4876, Sigma, The Netherlands) 2% in 70% isopropanol (Order No. 1.09634.1000, Merck, Netherlands) in water, ready for use within 3 weeks
- Pipette with a capacity of 50 µl of fluid

Method

- Selection of endoscope to be examined
- Choose an endoscope that contains clearly visible contamination / blood
- Label the endoscope
- Clean the endoscope in the usual manner.

Assessment of the cleaned endoscope

- Check the cleanliness of the object to be examined by visual observation. Pay attention to spots, circles, colour variations, foreign materials, etc. Note the observation.
- Apply 50µl water on a swab and polish the surface of the object tightly.
- Check the cleanliness of the swab to see if the object came off. Note the observation.
- Additionally apply 50µl ninhydrin solution on the swab and incubate the swab during 3.5 minutes.
- Check the swab on a purple coloration to see if the protein from the object stained. Note the observation.

[26] See Tijdschrift voor Hygiëne en Infectiepreventie nr.1 February 2003, p. 9-14.

freely provided the SFERD is listed as the author

Appendix 12 - Hemoglobin swab test

By making use of the (pseudo) peroxidase activity of hemoglobin traces of blood residues can be detected. Even a small amount of 0.1 mg dried and denatured blood gives a colour reaction that is clearly visible. The peroxidase activity of hemoglobin works as a catalyst in the presence of hydrogen peroxide in the oxidation of chromogen, which is shown by a clearly visible colour reaction. Blood residues become visible within a few seconds as an intense blue colour reaction.

The peroxidase reaction in blood even gives a positive result after the action of heat, alkali and aldehydes. Oxidising process chemicals such as hydrogen peroxide, can negatively affect the test. This method is therefore not suitable to detect blood traces on instruments that have been treated with such chemicals.

Materials
TMB test, comprising:
0.1% tetramethyl benzidine (TMB) in 5% acetic acid;
3% hydrogen peroxide solution.
1% SDS solution, for rinsing the lumen.

Activate 1 ml of TMB solution by adding 4 drops of 3% hydrogen peroxide solution. This solution is then ready for use.
Note: A ready-to-use TMB solution is available from the suppliers of chemicals used in analytical laboratories.

Equipment
- Test tubes;
- Cotton swabs (free from peroxidase; test!);
- 1 ml pipettes;
- Injection Syringes, 10 ml, for rinsing the lumen.

Selection of the endoscope to be examined
- Choose an endoscope that contains clearly visible blood.
- Label the endoscope
- Clean the endoscope in the usual manner.

Sample collection
Direct method
Activated TMB solution can be applied directly on the surfaces of the endoscope with a dropper or cotton swab to visualise blood residues in situ.

Swab method
Fill a test tube with 1 ml of activated TMB solution. The outer surfaces of the endoscope can be sampled with a cotton swab. If the surfaces are dry, the swab must first be moistened with a drop of water or 1% SDS solution.
Place the swab into the activated TMB solution. Check in advance whether the swab itself gives no colour reaction by performing a blank test.

Rinse Method for hollow instruments
Blood residues in lumen can be determined by spraying the lumen with a few millilitres of 1% SDS solution. The presence of hemoglobin can be demonstrated with micro hematuria dipsticks.

Acceptance criteria
The result of the cleaning process is acceptable if there are no blood residues visible in any of the samples. If the micro hematuria dipsticks are used, a result of more than 10 hemoglobin molecules per micro litre of eluate indicates that there were traces of blood present in the lumen.

Safety
Handling of chemicals
The information provided by the manufacturer of the chemicals, e.g. safety data sheets, must be adhered to. Where necessary, protective clothing, examination gloves and safety goggles must be worn.

Waste disposal
All chemicals should be disposed of in accordance with the regulations of the organisation concerned. Instruments that have been into direct contact with the activated TMB solution or are flushed or wiped with a SDS solution should be re-cleaned and disinfected again.

freely provided the SFERD is listed as the author

Appendix 13 – Release form flexible endoscopes

Release form Flexible Endoscopes

Washer-disinfector:

Date:

Time	Endoscope number	Tubes connected	Channel separator present	Entire programme completed	Control by

Appendix 14 – Schedule of requirements for washer-disinfector

I	**Aim of the washer-disinfector**				
	Cleaning and disinfection of flexible endoscopes and their accessories.				
II	**Interaction with endoscopes en their accessories**				
	All types of flexible endoscopes and accessories have to be disinfected according to the prescribed procedure				
III	**Patient categories**				
	N/A				
IV	**Users**				
	Employees department CSA, employees department inpatient or outpatient examination.				

		Requirement/ Demand			Explanation
1. Legal requirements			**Yes**	**No**	
Medical Directive	***1.1***	The washer-disinfector has a CE-label according to Medical Device Directive 93/42/EC.			
NEN-standard	***1.2***	The washer-disinfector meets the EN ISO 15883-1en EN ISO 15883-4			
R8152	***1.3***	The washer-disinfector meets the standard commission directive 1994/R8152 on sterilisation and sterility.			
NEN 10601	***1.4***	The washer-disinfector meets the electricity safety standard (NEN 10601).			
NEN-EN-IEC 61010-2-040:2005	***1.5***	The washer-disinfector meets the safety requirements for electronic equipment - Part 2-040: Special requirements for sterilisers and washer-disinfectors used to treat medical supplies.			
NEN 1006	***1.6***	The connections of the washer-disinfector meet the requirements of the water supply company (NEN 1006).			
Wip guidelines	***1.7***	The washer-disinfector meets the directive "Cleaning and disinfection of endoscopes "WIP"", (www.wip.nl).			
Occupational health safety and environment	***1.8***	The washer-disinfector meets the occupational health and safety law (www.arbo.nl).			
2. Validation			**Yes**	**No**	
	2.1	The cleaning and disinfection processes are validated, a validation report of this should be present (bring along copy).			
	2.2	There is an installation qualification program/protocol (provide programme/protocol).			
	2.3	There is a qualification program/protocol on the release of the process (provide programme/protocol).			
	2.4	The supplier has a list of critical process parameters (including criteria) that can/should be validated (enclose list)			
	2.5	The supplier provides an education/training for external validator (certificate is issued).			
	2.6	Indicate how the education / training is structured and which validators have attended this (enclose list validators).			
	2.7	The supplier provides a release report and a validation report directly after installation.			
3. Occupational health and safety and environment			**Yes**	**No**	
	3.1	Supplier indicates the water consumption (specify consumption).			
	3.2	Supplier indicates energy consumption (specify consumption).			
	3.3	The supplier/ manufacturer accepts the return of the washer-disinfector that needs to be replaced			
	3.4	The agents that are applied in the detergent and disinfectant are permitted according to the discharge permit			
	3.5	The detergent and disinfectant are deliverer in an appropriate UN approved package.			
	3.6	A safety sheet (PDF) regarding the detergent and disinfectant is available **(deliver)**.			
	3.7	Indicate the average amount of residual liquid in the storage tank			
	3.8	The washer-disinfector is equipped with facilities that prevent - that substances is released into the environment; - that substances remain in the user-accessible areas of the units; - that substances remain on the treated endoscopes?			
	3.9	There is an appropriate working height according to occupational health and safety standard **(provide specified working heights).**			
	3.10	There is an extraction system on the washer-disinfector (specify size).			
	3.11	The noise level is during the entire process _ <65dB (A) (provide test report).			
4. Requirements regarding Technique			**Yes**	**No**	
Technical aspects	***4.1***	The washer-disinfector should be suitable for all types of flexible endoscopes used in the hospital (provide declaration).			
	4.2	Malfunctions or incomplete processes are reported with both a visual and an audible signal.			
	4.3	During the entire process, the endoscope is tested for leak tightness.			
	4.4	The washer-disinfector is equipped with an automatic test that identifies blockages during the process.			
	4.5	The washer-disinfector features a continuous channel connection check for each connected channel (enter maximum number of channels that are monitored).			
	4.6	The washer-disinfector gives a signal when preventive maintenance is required in a timely manner			
	4.7	Interchanging / connecting the detergent and disinfectants not possible (describe measure).			
	4.8	In case of a broken sensor, there is a provision to prevent flooding.			
	4.9	There is leak tray for the detergent and disinfectant. Specify the volume that can be received.			

freely provided the SFERD is listed as the author

4.10	All parts are easily accessible for maintenance and repair. (deliver installation guide / pre-installation guide)			
4.11	All parts are resistant to the chemicals to be used.			
4.12	Data storage: there is a facility to prevent data loss.			
4.13	The washer-disinfector is resistant to power failures. (Specify).			
4.14	There is a facility to prevent backflow of water from the water compartment to the water supply system.			
4.15	*Can the following processes be interrupted independently by authorized personnel?* *-cleaning;* *- flushing* *- disinfection;* *- discharge-disinfectant;* *- flushing microbiologically safe water;* *- production microbiologically safe water;* *- drying.*			
4.16	What is the distance of the contact-area between washer-disinfector and the endoscope?			
4.17	The machine features a drain for water control.			
4.18	The machine features a bacteria filter monitor.			
4.19	The manufacturer establishes a filtration plan on behalf of the water supply and provides advice on the installation of the filters.			
4.20	The washer-disinfector can communicate with existing data management systems, at the time of purchase. Please indicate to which systems it can be linked.			
5. Requirements regarding the process		**Yes**	**No**	
5.1	The washer-disinfector operates according to the pass principle (clean/contaminated separated).			
5.2	The program cannot be continued after interruption of the process.			
5.3	The endoscope is not released if the process is not entirely completed.			
5.4	The process consists of at least the phases: pre-cleaning, cleaning, flushing, disinfecting, rinsing.			
5.5	The phase of the process is shown on the display			
5.6	Process parameters can be changed only by authorised personnel.			
5.7	The door can only be opened at the contaminated side after interruption of the process.			
5.8	Indicate the process time (specify the **process duration per run**).			
5.9	Indicate the consumption of detergents (specify costs **per run**).			
5.10	Indicate the consumption of disinfectant (specify costs per run).			
6. Cleaning and disinfection		**Yes**	**No**	
6.1	Detergent and disinfectant should be provided with a CE qualification.			
6.2	The washer-disinfector is suitable for all brands of CE approved detergents and disinfectants.			
6.3	The washer-disinfector is suitable for disinfection with per acetic acid.			
6.4	The product information of the washer-disinfector product contains information on cleaning and disinfection temperatures. (provide product information)			
6.5	The machine has a self-disinfection process.			
6.6	The washer-disinfector makes a notification if the disinfectant container is empty.			
6.7	The washer-disinfector makes a notification if the detergent container is empty.			
6.8	There is a check on the dosage of: -disinfectant; -detergent			
6.9	Dosage, exposure time and temperature of the detergent and disinfectant should be established in the programs. It is indicated in the documentation which programs are available. (provide documentation)			
6.10	The equipment operates with a rinse cycle with bacteria-free water to prevent residues of detergent and disinfectant (BS standard R4101).			
7. Requirements regarding support / education		**Yes**	**No**	
7.1	There is an English instruction manual available.			
7.2	There are English operational and load regulations available.			
7.3	There is a protocol with respect to corrective, preventive and inspective maintenance available for the technicians (certificate issued).			
7.4	The technicians are trained for both corrective and preventative maintenance.			
7.5	A technical manual is delivered.			
7.6	The supplier has access to an English speaking technical helpdesk.			
7.7	The supplier provides an training for the user (certificate issued).			
7.8	The supplier provides connection diagrams for all types of flexible endoscopes used in the hospital.			
8. Requirements regarding usability		**Yes**	**No**	
8.1	The washer-disinfector has an ergonomic operation, which is simple with minimal contact moments.			
8.2	In case of an alarm or notification, the machine gives a clear description of the problem identified and gives an instruction for the solution at user level.			
8.3	The (un)loading doors can be hygienically opened.			
8.4	The machine provides logical support by means of on-screen instructions during operation.			
9. Requirements regarding traceability and regsitration		**Yes**	**No**	
9.1	The functionality for the registration of endoscope, charge, process data, date and time, patient, specialist and operator is present.			
9.2	Each disinfection cycle, the data recorded and stored digitally (eg concerning machine, patient, scope, a specialist, and process flow)			
9.3	The washer-disinfector can communicate with internal control systems and networks (specify).			
9.4	The washer-disinfector provides the ability to generate management information (specify).			
10. Installation requirements		**Yes**	**No**	
10.1	Draws and measurements of the installation facilities (drainage, ventilation, exhaust, water) are delivered.			
10.2	Specific requirements for water quality are delivered.			
11. Requirements regarding maintenance		**Yes**	**No**	
11.1	The supplier proposes maintenance contracts, including costs.			
11.2	The supplier proposes a price list of most commonly available parts.			
11.3	The company accepts the Standard Service Agreement (SSO) of the FHI.			
11.4	All required components can be delivered within 24 hours.			
11.5	The supplier provides passwords and codes for repair and maintenance of hardware and software or mechanical components			
11.6	A technician of the supplier can be present within 24 hours.			
11.7	A loan washer-disinfector can be made available within 2 days			
11.8	For software and hardware problems, the maximum downtime is 24 hours.			
11.9	Software licenses should be valid for the lifetime cycle of the device.			
11.10	Software and hardware updates and features for software and hardware updates can be performed on behalf of modalities and control for at least 10 years.			

Appendix 15 – Requirements for flexible endoscopes

I	**Aim of the flexible endoscopes.**					
	For non-invasive diagnostic and therapeutic examinations					
II	**Interaction with washer-disinfector, drying cabinet, and medical supplies.**					
	All types of flexible endoscopes and accessories have to be disinfected according to the prescribed procedure					
III	**Patient categories**					
	Diverse					
IV	**Users**					
	Employees department CSA, employees department inpatient or outpatient examination.					
			Requirement/ Demand			**Explanation**
1. Legal requirements				**Yes**	**No**	
	Medical Directive	***1.1***	The endoscope has a CE-label according to Medical Device Directive 93/42/EC.			
	NEN 10601	***1.2***	The endoscope meets the electricity safety standard (NEN 10601).			
2. Requirements regarding Technique				**Yes**	**No**	
	Technical aspects	***2.1***	The endoscope can be cleaned and disinfected automatically in all washer-disinfectors present in the hopitals.**(compatibility detergents and disinfectants).**			
		2.2	All parts are resistant to the chemicals to be used.			
		2.3	The endoscope should be designed in such a way that it can be properly cleaned, both manually and automatically, and disinfected.			
		2.4	The endoscope can communicate with the, at time of purchase, present and future, data management systems.			
		2.5	The manuals provides a list of compatible devices and accessories (for research and cleaning / disinfection).			
		2.6	The endoscope is resistant to drugs, bodily fluids and agents used during the examination.			
		2.7	The endoscope can be positioned and connect to the existing drying cabinets			
		2.8	Specifications for maximum pressure and pressure differences in the channels is indicated			
3. Cleaning, disinfection, and sterilisation				**Yes**	**no**	
		3.1	The temperatures for cleaning, disinfection, and sterilisation are indicated in the product information of the endoscope			
		3.2	The product information shows to which detergent, disinfectant, and sterilisation agent the endoscope is resistant.			
		3.3	The endoscope is steam sterilisable (121gr.).			
		3.4	The endoscope is steam sterilisable (134gr.).			
		3.5	The endoscope is formaldehyde sterilisable.			
		3.6	The endoscope is ethylene oxide sterilisable.			
		3.7	The endoscope is plasma sterilisable.			
4. Requirements regarding support / education				**Yes**	**no**	
		4.1	There is an English instruction manual available.			
		4.2	There is an English operational regulation available.			
		4.3	There is a protocol with respect to corrective, preventive and inspective maintenance available for the technicians (certificate issued).			
		4.4	There is a protocol with respect to corrective, preventive and inspective maintenance available for the technicians			
		4.5	A technical manual is delivered.			
		4.6	The supplier has access to an English speaking technical helpdesk.			
		4.7	The supplier provides a manual for the user.			
		4.8	A cleaning and disinfection directive is provided and education in this is arranged on request.			
		4.9	The supplier provides training on request.			
5. Requirements regarding usability				**Yes**	**no**	
		5.1	Assessment following trial placement.			
6. Requirements regarding traceability and registration				**Yes**	**no**	
		6.1	The endoscope contains an identifier, that can be read by the registration software present in the hospital.			
7. Installation requirement				**Yes**	**no**	
		7.1	The endoscope is compatible with the processor and light source present.			
8. Requirements regarding maintenance				**Yes**	**no**	
		8.1	The supplier proposes maintenance contracts.			
		8.2	The supplier proposes a price list of most commonly available parts.			
		8.3	The company accepts the Standard Service Agreement (SSO) of the FHI.			
		8.4	All required components can be delivered within 24 hours.			
		8.5	Defect endoscopes are repaired within a predetermined period. During this period, a loan scope is available.			
		8.6	During at least 10 years, the parts are available.			
		8.7	A technician of the supplier can be present within 24 hours.			
		8.8	Maintenance and repair can be carried out by medical technicians (special tools can be delivered)			

freely provided the SFERD is listed as the author

Appendix 16 – Schedule of requirements for drying cabinet

I Aim of drying cabinet

Drying and storage of flexible endoscopes and their accessories (both exterior and channels).

II Interaction with endoscopes and their accessories

All types of flexible endoscopes and accessories must be able to be dried in accordance with the prescribed procedure.

III Patient categories

Various

IV Users

Employees department CSA, employees department inpatient or outpatient examination.

		Requirement/ Demand			Explanation
1. Legal requirements			**yes**	**no**	
Medical Directive	***1.1***	The drying cabinet has a CE-label according to Medical Device Directive 93/42/EC.			
NEN-standard	***1.2***	Not available yet.			
NEN 10601	***1.3***	The drying cabinet meets the electricity safety standard (NEN 10601).			
Wip guidelines	***1.4***	The drying cabinet meets the directive "Cleaning and disinfection of endoscopes "WIP", (www.wip.nl).			
Occupational health safety and environment	***1.5***	The drying cabinet meets the occupational health and safety law (www.arbo.nl).			
2. Validation			**yes**	**no**	
	2.1	The drying process is validated, of which a validation report is available (provide copy).			
	2.2	There is an installation qualification program/protocol (provide programme/protocol).			
	2.3	There is a qualification program/protocol on the release of the process (provide programme/protocol).			
3. Occupational health and safety and environment			**yes**	**no**	
	3.1	Supplier indicates the compressed air consumption (specify consumption).			
	3.2	Supplier indicates energy consumption (specify consumption).			
	3.3	The supplier/ manufacturer accepts the return of the drying cabinet that needs			
	3.4	There is an appropriate working height according to occupational health and safety standard **(provide specified working heights).**			
	3.5	The noise level is during the entire process _ <65dB (A) (provide test report).			
4. Requirements regarding Technique			**yes**	**no**	
Technical aspects	***4.1***	The drying cabinet should be suitable for all types of flexible endoscopes used in the hospital (provide declaration).			
	4.2	Malfunctions or incomplete processes are reported with both a visual and an audible signal.			
	4.3	The drying cabinet features a continuous channel connection check.			
	4.4	The drying cabinet features a continuous flow monitor for each connected channel.			
	4.5	The drying cabinet gives a signal when preventive maintenance is required.			
	4.6	There is good accessibility to all components relating to the maintenance and repair.			
	4.7	A no-break facility is present, for data storage.			
	4.8	The drying cabinet is resistant to power failures (specify)			
	4.9	The drying cabinet should be designed in such a way that the contact surface with the endoscope is minimal.			
	4.10	The drying cabinet contains a bacteria filter monitor.			
	4.11	The drying cabinet can communicate with existing data management systems, at the time of purchase.			
5. Requirements regarding the process			**yes**	**no**	
	5.1	The program cannot be continued after interruption of the process.			
6. Drying process			**yes**	**no**	
	6.1	The process parameters are addressed in the product information of the drying cabinet (time/temperature/pressure).			
	6.2	The drying cabinet features continuous temperature monitoring.			
	6.3	Drying time should be established in the programs.			
	6.4	The equipment operates with appropriate drying cycle in bacteria-free compressed air to prevent contamination of the scope.			
	6.5	There is overpressure in the cabinet.			

7. Requirements regarding support / education		**yes**	**no**	
	7.1 There is an English instruction manual available.			
	7.2 There are English operational and load regulations available.			
	7.3 There is a protocol with respect to corrective, preventive and inspective maintenance available for the technicians.			
	7.4 The technicians are trained for both corrective and preventative maintenance.			
	7.5 A technical manual is delivered.			
	7.6 The supplier has access to an English speaking technical helpdesk.			
	7.7 The supplier provides an training for the user.			
8. Requirements regarding usability		**yes**	**no**	
	8.1 The drying cabinet is easy to use (describe)			
	8.2 In case of an alarm or notification, the drying cabinet gives a clear description of the problem identified and gives an instruction for the solution at user level.			
	8.3 The (un)loading doors can be hygienically opened.			
	8.4 The drying cabinet provides logical support by means of on-screen instructions during operation.			
9. Requirements regarding traceability and registration		**yes**	**no**	
	9.1 The functionality for the registration of endoscope, charge, process data, date and time, patient, specialist and operator is present.			
	9.2 The data are registered each drying cycle centrally and decentralised and digitally saved among others drying cabinet, patiënt, scope, specialist, procedure			
	9.3 The drying cabinet can communicate with the management system.			
10 Installation requirements		**yes**	**no**	
	10.1 Draws and measurements of the installation facilities (drainage, ventilation, exhaust, water) are delivered.			
	10.2 Specific requirements for water quality are delivered.			
11 Requirements regarding maintenance		**yes**	**no**	
	11.1 The supplier proposes maintenance contracts.			
	11.2 The company accepts the Standard Service Agreement (SSO) of the FHI.			
	11.3 All required components can be delivered within 24 hours.			
	11.4 The supplier provides passwords and codes for repair and maintenance of hardware and software or mechanical components			
	11.5 A technician of the supplier can be present within 24 hours.			
	11.6 A loan washer-disinfector can be made available within 2 days .			
	11.7 For software and hardware problems, the maximum downtime is 24 hours.			
	11.8 Software licenses should be valid for the lifetime cycle of the device.			
	11.9 Software and hardware updates and features for software and hardware updates can be performed on behalf of modalities and control for at least 10 years.			

freely provided the SFERD is listed as the author

Appendix 17 – Audit form endoscopy

Questionnaire on behalf of endoscopy **Appendix 17**

Dep. GE/urology/pulmonologist/ENT

Department/location:	
Audited:	
Auditor (s):	
Date:	

describe departement, amount en type of endoscopes en endo-washerdesinfector

Comments:

answer the questions by entering 'yes', 'no' or 'partly' in the appropriate column

1	Policy regulations cleaning and disinfection endoscopes	yes	no	partly	notes / comments / advice
1.1	The endoscope policy is established at departmental level	yes			
1.2	Endoscopes and accessories, used in non-sterile body cavities, are disinfected by machine		no		
1.3	Endoscopes and accessories, used in non-sterile body cavities, are sterilised			partly	
1.4	It is clear how the responsibilities for cleaning and disinfection of endoscopes are divided.	yes			
1.5	These are recorded in writing		no		date:
1.6	Used biopteurs, loops etc. are sterilised or disposables are used				
	Work takes place according to correct principles, as follows:				
1.7	manual leak test				
1.8	pre-cleaning				
	process steps in disinfector:				
1.9	leak test				
1.10	cleaning				
	(possibly) rinsing				
1.11	disinfection				
1.12	final rinse				
1.13	drying				

	recommendation / point for improvement	priority
1a		
1b		
1c		
1d		

answer the questions by entering 'yes', 'no' or 'partly' in the appropriate column

2	Implementation manual cleaning endoscope	yes	no	partly	notes / comments / advice
2.1	The method for cleaning is established in the protocol				Date protocol:
2.2	The protocol is available near the sink and easy to look into for everyone.				
2.3	During manual cleaning, non-sterile gloves are worn				
2.4	For cleaning, a solution of enzymatic cleaner in lukewarm water is used.				used product:
2.5	Concentration of solution according to regulation				used concentration:
2.6	This solution is refreshed daily or in case of visual contamination				frequency:
2.7	Before immersion a leak test is carried out.				
2.8	The scope is placed into the counter immediately after the examination.				maximum time:
2.9	The scoop is wiped off on the exterior with a gauze or washcloth.				
2.10	The suction cap is disassembled, sprayed with water, brushed, soaked in cleaning solution and then rinsed with water				
2.11	Ring, caps and any other loose parts are brushed, soaked in cleaning solution and then rinsed with water.				
2.12	Caps and other spare parts are ultrasonically treated				

	recommendation / point for improvement	priority
2a		
2b		
2c		

answer the questions by entering 'yes', 'no' or 'partly' in the appropriate column

3	Ultrasonic Bath	yes	no	partly	notes / comments / advice
3.1	The ultrasonic bath is filled with water and ultrasonic fluid and set at the right temperature of <40 degrees C.				brand ultrasonic: used product:
3.2	Concentration solution according to regulation				used concentration:
3.3	The ultrasonic fluid is refreshed at least daily				
3.4	A load regulation is present				date regulation:
3.5	This regulation is located in the vicinity of the ultrasonic bath and easily accessible for everyone				
	The load regulation contains the following actions;				
3.6	The products are at least 5 minutes in the ultrasonic bath				
3.7	The products are spread as much as possible with minimum shading.				
3.8	Small products that can float, go into a closed basket.				
3.9	The bath is closed with a lid when it is operating				

	recommendation / point for improvement	priority
3a		
3b		

freely provided the SFERD is listed as the author

answer the questions by entering 'yes', 'no' or 'partly' in the appropriate column

4	Loading the washer-disinfector	yes	no	partly	notes / comments / advice
4.1	A load regulation is present				disinfector type:
4.2	This is located in the vicinity of the machine and is easily accessible for everyone.				date regulation:
	The load regulation includes the following actions:				
4.3	Ring, caps and any other loose parts are placed in a basket in the washing machine.				
4.4	The scope is placed into the machine, in such a way that the entire distal part is located "free" (e.g. disappears in the mouth of				
4.5	There is a system that avoids connection errors.				
4.6	The load regulation describes which tubes should be connected to which channels				

	recommendation / point for improvement	priority
4a		
4b		
4c		

answer the questions by entering 'yes', 'no' or 'partly' in the appropriate column

5	Functioning of the machine	yes	no	partly	notes / comments / advice
5.1	The outlines of the (technical) function are clear to the staff				
5.2	An operation regulation is located in the vicinity of the machine and easily accessible for everyone				date regulation:
5.3	A procedure is established in writing, how to act in case of malfunctions; within reach and accessible for everyone.				date procedure:
5.4	The process parameters and process programs can only be changed by appropriately authorised personnel.				authorised persons
5.5	The endoscope compartment is locked during the process. If the process is interrupted, continuation of the same process is impossible thereafter.				
5.6	The washing machine features an automatic leak test.				
5.7	The washing machine features pressure control of the channels by which obstructions are identified.				
5.8	The washing machine is disinfected weekly by means of a self-disinfection programme.				
5.9	The washing machine is frequently decalcified				
5.10	The washing machine has a provision that precludes recontamination during the final rinse (bacteria-free water).				means:
5.11	The washing machine features a process counter serving periodic maintenance.				
5.12	The washing machine features a possibility to enter data serving patient tracking.				
5.13	The washing machine is preventively maintained by an external or internal technical expert once a year.				Executor:
5.14	The control and release after regular major maintenance and major repairs is recorded in a protocol on validation and release of endoscope washers.				Date protocol: Validation by: Release by:

	recommendation / point for improvement	priority
5a		
5b		

answer the questions by entering 'yes', 'no' or 'partly' in the appropriate column

6	Cleaning and disinfection of endoscope washing machine	yes	no	partly	notes / comments / advice
6.1	The washing machine has a system to enable control the dosage of detergent and disinfectant.				which system:
6.2	The washing machine is equipped with connections which prevent change of detergent and disinfectant.				
6.3	Detergent and disinfectant are in a closed cabinet according to FIFO principle				storage quantity:
6.4	The method for replacing the barrels of detergent and disinfectant is described in a protocol.				
6.5	This protocol is in the vicinity of the machine and is easily accessible for everyone.				
6.6	Replacing the barrels with detergent and disinfectant is in accordance with this protocol.				

	recommendation / point for improvement	priority
6a		
6b		

answer the questions by entering 'yes', 'no' or 'partly' in the appropriate column

7	Execution drying endoscope in drying cabinet	yes	no	partly	notes / comments / advice
7.1	The method of drying the endoscope is described in a protocol.				date protocol
7.2	The protocol is located in the vicinity of the drying cabinet and easily accessible for everyone.				
7.3	Endoscopes which are not used within 4 hours after disinfection, are dried in the drying cabinet for at least 30 minutes.				set drying time:
7.4	Endoscopes which are not used for a period > 4 hours, without drying, are disinfected before use again.				
7.5	There is a policy (in writing) on how long endoscopes may hang in the drying cabinet.				applied storage life
7.6	The drying cabinet is cleaned domestically once a month. Schedule of cleaning is available and signed.				
7.7	Periodic maintenance and frequency of change of filters is included in a protocol.				date protocol: frequency replacements:

	recommendation / point for improvement	priority
7a		
7b		

answer the questions by entering 'yes', 'no' or 'partly' in the appropriate column

8	Transportation endoscopes	yes	no	partly	notes / comments / advice
8.1	The mode of transportation of (contaminated and clean) endoscopes is described in a protocol				date protocol:
8.2	The protocol is available on the ward and easily accessible for everyone.				
8.3	The transportation of endoscopes is limited from disinfection area to adjacent examination or storage area				
	If no "yes" is entered at 8.3, following questions are addressed.				specify transport:
8.4	Transportation of endoscopes takes place in a closed transport system				system:
8.5	At transportation of endoscopes, it is clear whether the endoscope is clean or contaminated.				
8.6	Transport system is sealed in case of clean endoscopes.				
8.7	Transport system is cleaned and disinfected after transportation of contaminated endoscopes.				method: frequency:

	recommendation / point for improvement	priority
8a		
8b		

freely provided the SFERD is listed as the author

	answer the questions by entering 'yes', 'no' or 'partly' in the appropriate column				
9	**Registration of data**	**yes**	**no**	**partly**	**notes / comments / advice**
	A logbook is kept for each disinfector (whether automated or not) in which the following items are recorded.				system:
9.1	-Date				
9.2	-Patient number				
9.3	-Number of the endoscope				
9.4	-Name / code of loading employee				
9.5	-Name / code of operating endoscopy specialist				
9.6	-Name / code of unloading employee				
	When replacing detergent and disinfectant, the following information is recorded:				system:
9.7	-Date of replacement				
9.8	Batch number detergent / disinfectant				
9.9	Machine Number				
9.10	Signature of the employee who (s) has replaced the container				
9.11	Signature control colleague				

	recommendation / point for improvement	**priority**
9a		
9b		

	answer the questions by entering 'yes', 'no' or 'partly' in the appropriate column								
10	**Hygiene & Infection Prevention**	**yes**	**no**	**partly**	**notes / comments / advice**				
	Hygiene practice endoscopy								
10.1	There is a separate routing between clean and contaminated								
10.2	No rings, watches and / or bracelets worn								
10.3	After every scopy the scopist washes or disinfects his/her hands before touching other things.								
10.4	After every scopy the assistant washes or disinfects his/her hands before touching other things.								
10.5	After every scopy hands are washed and disinfected after taking off the gloves.								
	hygiene disinfector								
10.6	The top of the lid, sealing edges, and operation panel are domestically washed and subsequently disinfected at the end of the day				disinfectant: checklist present:				
	The endoscopist wears:								
10.7	Gloves								
10.8	Protective coat								
10.9	Mask (if suspecting pulmonary tuberculosis)								
10.10	Protective glasses or splash goggles								

freely provided the SFERD is listed as the author

	answer the questions by entering 'yes', 'no' or 'partly' in the appropriate column									
	The assistant wears:									
10.11	Gloves									
10.12	Protective coat									
10.13	Mask (if suspecting pulmonary tuberculosis)									
10.14	Protective glasses or splash goggles									
	Facilities									
10.15	Sufficient hand washing facilities available.									
10.16	The tap has elbow or foot operation.									
10.17	Alcohol dispenser available.									
10.18	Soap dispenser available									
10.19	Towel dispensers with paper towels available.									
10.20	Foot-operated bin available (at least not manually)									

	recommendation / point for improvement	**priority**
10a		
10b		
10c		
10d		
10e		

answer the questions by entering 'yes', 'no' or 'partly' in the appropriate column

11	Staff expertise	yes	no	partly	notes / comments / advice
11.1	Which staff members carry out the disinfection?				function:
11.2	At least vocational level (medical nurse)				
	Employees are trained expertly?				
11.3	Complete settling-in programme				
11.4	Training at supplier of disinfector				
11.5	Training at supplier of scopes				
11.6	Endoscopy training (location)				
	Employees have frequent in-service training				
11.7	annual endoscopy conference				
11.8	annual internal training				
11.9	annual training at supplier				

	recommendation / point for improvement	priority
11a		
11b		

answer the questions by entering 'yes', 'no' or 'partly' in the appropriate column

12	Quality assurance	yes	no	partly	notes / comments / advice
12.1	Protocols are updated with a predetermined frequency				
12.2	It is clear who has responsibility over authorisations				
	The machine is validated on a predetermined frequency:				external/ internal: who:
12.3	technically				frequency:
12.4	chemically				frequency:
12.5	microbiologically				frequency:
12.6	use (audit)				frequency:
	The endoscopes are validated on a predetermined frequency:				external/ internal: who:
12.7	technically				frequency:
12.8	chemically				frequency:
12.9	microbiologically				frequency:
12.10	use (audit)				frequency:
12.11	the scope management plan is evaluated annually				

	recommendation / point for improvement	priority
12a		
12b		
12c		

freely provided the SFERD is listed as the author

answ er the questions by entering 'yes', 'no' or 'partly' in the appropriate column

13	Area	yes	no	partly	notes / comments / advice
13.1	There is a separate area for cleaning and disinfection of endoscopes				
13.2	Is there sufficient surface area for (spatial) separation of clean and contaminated endoscopes				
13.3	Are there enough technical occupational health and safety features such as splash screens, air treatment, exhaust etc.				air / suction:l splash screen:
13.4	Is there enough working space serving the pre-cleaning of contaminated and assembly of clean endoscopes				enlarged sink: separated worktops:
13.5	Is there a separate administrative workplace available				
13.6	Is there a separate area available for drying and storage of endoscopes				
13.7	The finishing of floors, walls, borders and ceiling is in accordance with Construction College (smooth, shock-resistant, resistant to				

	recommendation / point for improvement	priority
13a		
13b		
13c		
13d		

Appendix 18 – Audit form endoscopy – Medical Technology

Questionnaire on behalf of endoscopy management	**APPENDIX 18**
Department of Medical Technology	
Department / Location:	
Audited:	
Auditor (s):	
Date:	
Type of disinfector(s):	
Type of endoscopes:	

freely provided the SFERD is listed as the author

	answer the questions by entering 'yes', 'no' or 'partly' in the appropriate column				
T.1	**Purchase and installation washer-disinfector**	**yes**	**no**	**partly**	**explanation**
1.1	The purchase of washer-disinfectors occurs according to ISO NEN EN 15883?				
1.2	The purchase of washer-disinfectors occurs in accordance with a predetermined set of requirements, established in collaboration with users, Expert, TD, ID, procurement, etc?				
1.3	Does the quality of water supply to the washer-disinfector comply with the directive R 4101-1 of the guideline Sterilization and Sterility?				used water:
1.4	Is a compatibility statement, including the endoscopes and the cleaning and disinfecting agents used, available for every washer-disinfector?				
1.5	*Have agreements been made with regard to the washer-disinfector, about:*				
1.5.1	* Who performs maintenance (during warranty)?				executor:
1.5.2	* dates of regular preventive maintenance?				frequency:
1.5.3	* activities to be carried out during preventive maintenance?				protocol present:
1.5.4	* the validation protocol or checklist that is checked?				
1.6	Are washer-disinfectors validated before commissioning?				
	Are washer-disinfectors validated at the following moments:				
1.7.1	* at purchase				
1.7.2	* after repair (external)				
1.7.3	* after maintenance (annually major)				
1.7.4	* If the washer disinfector is used for a new type of endoscope?				
1.8	is there a release procedure before commissioning of a washer-disinfector?				registration:
1.9	is an up-to-date technical logbook available for each washer-disinfector?				system:

	recommendation / point for improvement	**priority**
T.1a		
T.1b		

	answer the questions by entering 'yes', 'no' or 'partly' in the appropriate column				
T.2	**Use of washer-disinfector**	**yes**	**no**	**partly**	**explanation**
2.1	The process parameters and process programs can only be changed by appropriately authorised persons				by:
2.2	The endoscope compartment is locked during the process. If the process is interrupted, continuation of the same process is impossible thereafter				
2.3	The washer-disinfector features an automatic leak test				
2.4	The washer-disinfector features pressure monitoring of the channels through which obstructions are detected				
2.5	The washer-disinfector has a provision that precludes recontamination during the final rinse (bacteria-free water)				means:
2.6	The washer-disinfector has a process counter, serving periodic maintenance				
2.7	The washer-disinfector is equipped with a possibility to enter data serving patient tracking				
2.8	The washer-disinfector is preventively maintained by an external or internal technical expert at least once a year				frequency:
2.9	control and release after regular major maintenance and major repairs are established in a validation and release protocol for washer-disinfectors				Date protocol: Validation by: Release by:
2.10	The washer-disinfector has a system that enables control of the dosage of detergent and disinfectant				
2.11	The washer-disinfector is equipped with connections which prevent change of detergent and disinfectant.				

	recommendation / point for improvement	**priority**
T.2a		
T.2b		

answer the questions by entering 'yes', 'no' or 'partly' in the appropriate column

T.3	User maintenance washer-disinfector	yes	no	partly	explanation
3.1	The water softener is frequently regenerated				
3.2	the coarse filter of the drying unit is replaced every xxx operating hours				frequency: …. Hours
3.3	The fine filter (sterile filter) is replaced every xxx operating hours				frequency: …. Hours
3.4	The washer-disinfector features pressure monitoring of the channels by which obstructions are detected				
3.5	The UV unit is maintained according to the Maintenance Manual				frequency: …. Hours
3.6	The filters in the wash room are cleaned frequently				frequency:
3.7	The filters in the water supply are frequently monitored				frequency:
3.8	The nozzles on the spray arm are frequently checked for patency				frequency:
3.9	The sealing rings of the leak detector are frequently checked and replaced if necessary				frequency:
3.10	The nozzles and tubes of the inset trolley are examined and cleaned frequently				frequency:

	recommendation / point for improvement	priority
T.3a		
T.3b		

answer the questions by entering 'yes', 'no' or 'partly' in the appropriate column

T.4	Other	yes	no	partly	explanation
4.1	there is regular maintenance of the drying cabinets				
4.2	the filters of the drying cabinets are frequently replaced				frequency:
4.3	the drying cabinets function with filtered dust-free air				
4.4	the drying cabinets have preset minimum drying time				drying time:
4.5	The suction channel of the drying cabinet is drained to the outside				
4.6	An up-to-date technical logbook is present for each drying cabinet				
4.7	Maintenance of the ultrasonic bath takes regularly place				frequency:
4.8	An up-to-date technical logbook is present for the ultrasonic bath				

	recommendation / point for improvement	priority
T.4a		

freely provided the SFERD is listed as the author

answer the questions by entering 'yes', 'no' or 'partly' in the appropriate column

T.5	Purchase and commissioning of the endoscopes	yes	no	partly	explanation
5,1	The purchase of endoscopes occurs in accordance with a predetermined set of requirements, established in collaboration with users, Expert, TD, ID, procurement etc?				specify
5,2	Is a compatibility statement available for each endoscope, including the washer-disinfector and the detergent and disinfectant used?				
5,3	Have agreements been made at purchase of the endoscope, about:				
5.3.1	* who performs maintenance (during the warranty)?				
5.3.2	* dates of regular preventive maintenance?				
5.3.3	* activities to be carried out during preventive maintenance?				
5.3.4	* the validation protocol or checklist that is checked?				
5,4	are endoscopes technically checked at the following moments?				
5.4.1	* at purchase				
5.4.2	* after repair (external)				
5.4.3	* after maintenance (annually major)				
5,5	is there a release procedure before commissioning of an endoscope?				
5,6	is an up-to-date technical logbook available for each endoscope?				

	recommendation / point for improvement	priority
T.5a		
T.5b		

answer the questions by entering 'yes', 'no' or 'partly' in the appropriate column

T.6	Use of the endoscope	yes	no	partly	explanation
6.1	the endoscope has a unique code on behalf of automatic tracking and tracing				
6.2	the endoscope is preventatively maintained by an internal or external technical expert minimally 2 times a year				
	How is a loan endoscope registered?				specify

	recommendation / point for improvement	priority
T.6a		
T.6b		

T.7	User maintenance endoscope	yes	no	partly	explanation
7.1	The endoscope is tested for patency and functionality prior to use				

	recommendation / point for improvement	priority
T.7a		

Appendix 19 – Response form for contributions for improvement of the handbook

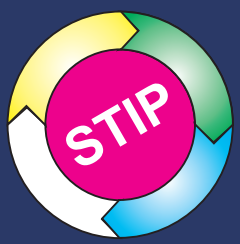
Remarks Standard Quality Handbook Flexible Endoscopes Cleaning and Disinfection, version:

Page	Paragraph / Line	Remark	Request or suggestion for alteration / modification

Date:
Contributor:
Institution:
E-mail:

You can send your response to the secretary of the SFERD:
J.vbergenhenegouw@hagaziekenhuis.nl

freely provided the SFERD is listed as the author



Stichting Trainingen Infectie Preventie

www.infectiepreventieopleidingen.nl